MINAmI

Micro-Nano integrated platform for transverse Ambient Intelligence applications

FP6 Contract: IST-034690

WP07 – Demonstration, validation & exploitation

Deliverable report

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Approvals

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V0.2	04/09/2009	Mobile phone application sections added	TID
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Section 1 - Executive summary

1.1 Description of the deliverable content and purpose

The main contents of this deliverable are the Installation Guide document and the User Manual document regarding the demonstrator created in Task 7.2 *Health monitoring & Homecare demonstrator* for Phase II. The purpose of this deliverable is to help users to install and use the Sleep logger and Reader & Charger prototype and the mobile application associated.

More specifically, the Installation Guide section describes the steps needed to install and configure the Sleep logger and Reader & Charger prototype and the *Health monitoring & Homecare* mobile application. On the other hand, the User Manual section explains how the user should make use of the demonstrator: Sleep logger and Reader & Charger prototype and mobile application. Therefore, it describes the Sleep logger and Reader & Charger prototype user interface and the mobile application user interface with the different options available to the user.

This document also contains a Test Report and a User Evaluation results related to Phase II. The Test Report specifies the test cases that have been tested. In addition, validation resutls of the sleep scoring algorithm are presented.

This deliverable is structured as follows:

Section 2 – Introduction: brief introduction to the whole document.

Section 3 –Installation Guide: contains the steps needed to install the different components regarding the demonstrator.

Section 4 – User Manual: includes the instructions for the user about how to use the different demonstrator components.

Section 5 – Test Report contains the different test cases that have been made to check demonstrator compliance and User Evaluation.

Glossary

Acronym	Signification
HW	Hardware
EEG	Electroencephalography
OS	Operating System
IMEI	International Mobile Equipment Identity
USB	Universal Serial Bus
URL	Uniform Resource Locator
PC	Personal Computer
SE	Standard Edition
JDK	Java Development Kit
SSL	Secure Socket Layer

Content

Section 2 - Introduction

Health monitoring & Homecare demonstrator was developed to assess the feasibility of the concept of ultra-light physiological data logger in sleep disorder studies. In the basic form, the patient uses the EEG Logger for collecting EEG and acceleration signal overnight and sends the data for automatic analysis using Logger Base and mobile phone. The system enables repeated measurements and provides feedback between recording sessions.

The patient initiates data logging in the evening by attaching the *Logger* on his/her forehead using adhesive electrodes. For data readout from the logger memory in the morning, the user puts the *Logger* on the *Logger Base*, which automatically performs data readout and recharges the logger batteries. The *Mobile Phone* is used to read the data from the base via Bluetooth and sending the data to Medical Server via 3G-connection. The Medical Server executes automatic analysis, provides user interface for the physician, and enables messaging with the patient's mobile phone.

The main content of this deliverable is the documentation needed for using the demonstrator system: The Installation Guide describes the steps needed to install and configure the *Health monitoring & Homecare* demonstrator system. The User Manual section describes the basic flow of operation during a sleep study for the patient. It also describes both the Logger Base user interfaces, and the mobile application user interface with the different options available to the patient. The User Manual also briefly describes for the physician the use of EEG Logger system and the Medical Server.

In addition, the document consist test resutls. In case of *Health monitoring & Homecare demonstrator* there are three groups of tests: Verification of the system againts test cases deved from requirements, validation of the sleep analysis algorithm againts manual sleep stage scoring, and finally user evaluation of the complete demonstrator system.

Section 3 - Installation guide

This section includes instructions for installing and configuring the EEG Logger / Logger base, Mobile application, and the Medical server.

3.1 EEG Logger and Logger Base

The EEG Logger and the Logger Base include fixed firmware; hence no configuration as such is needed.

The main configuration or maintenance activity for the physician or healthcare provider is to take care of the EEG Logger batteries. The state diagram is shown in Figure 1, and a more detailed description of the states can be found in Table 1.

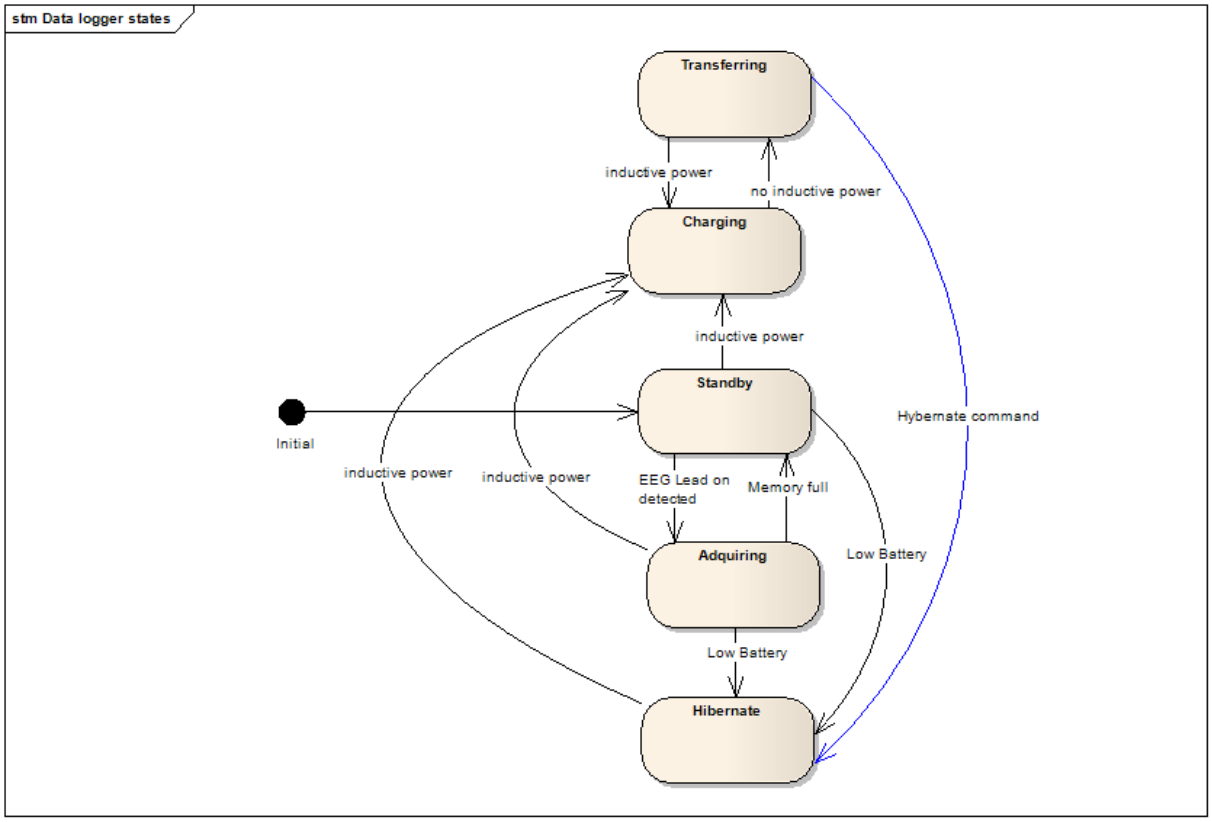

Figure 1 – State diagram of EEG Logger

Standby	The main idle mode when not operating. In this state, the data logger polls for EEG Lead On event every 10 seconds by analyzing valid data at the differential amplifier output.
Charging	This state is entered when the logger detects that power source is inductive. In this state, the battery is recharging and the logger accepts commands from the Logger base by capacitive coupling.
Acquiring	This state is entered when the logger detects

	good data at the EEG leads and begins recording. It will remain in this state until memory is full or low battery condition is detected, or placed on the base station.
Transmitting	This state is entered upon reception of a start data transmission command. Logger remains in this state while the base issues commands.
Hibernate	This state is entered upon detecting a battery low event. Detection of inductive power will make the logger to enter the Charging state. Power consumption is zero.

Table 1 – T7.2 Logger state description

When the EEG Logger is placed on Logger Base, battery-recharging takes place automatically. In the end of the 8-h recharging period, the Logger Base commands the EEG Logger to hibernate. *In order to take a hibernating logger back to stand-by mode, the operator shall place the EEG Logger on the Logger Base (see Figure 12) for some 10 seconds.*

Note After a prolonged storage time (say, weeks), the EEG Logger shall be reloaded before overnight registration.

3.2 Mobile device application

The mobile device application associated to *Health monitoring & Homecare demonstrator* runs on terminals with Symbian OS version S60 3rd edition.

MINAmI's mobile device applications are Symbian's 3rd party external applications (.sis files) that must be signed (.sisx files) so the device can confirm its authenticity and it came from the intended developer and is not a virus of some sort[1].

Environmental needs:

- Desktop computer or laptop with USB port or Bluetooth connection.
- MINAmI-enabled mobile device (Symbian OS version S60 3rd edition).
- MINAmI *Health monitoring & Homecare demonstrator* (T7.2 hereafter) mobile application signed.

There are two options for installing the MINAmI's mobile device application. For both of them Nokia PC Suite[2] software must be installed and configured:

- Option 1: Nokia PC Suite's install applications option.

[1] Nokia provides free digital certificates to sign any application for each terminal. To generate those certificates is needed the IMEI number of each device. The IMEI number is usually printed on the compliance plate under the battery or in the mobile device's box. It can also be get in most mobile devices typing the code **#06#* so it appears directly in the display. When the product is finished the certificate must be bought to Nokia to sign the application with it so it can be distributed for every terminal. In order to install the application, the provider must supply a valid signed application for the mobile device that is going to be used.

[2] Nokia PC Suite is a free software package for connecting your Nokia device to a compatible PC. The following address offers a complete tutorial with animated demonstrations that can give you an overview of what your Nokia device can do in tandem with your PC:
http://nds1.nokia.com/tutorials/support/global/phones/pc_suite/english/index.html

- Option 2: Windows Explorer's Nokia Phone Browser option.

3.2.1 Option 1: Nokia PC Suite's install applications

- Step 1
  Plug the mobile device in the USB port of the personal computer. In a few seconds a menu is visible in the mobile device, then select that it's going to be used the PC Suite (See Figure 2).

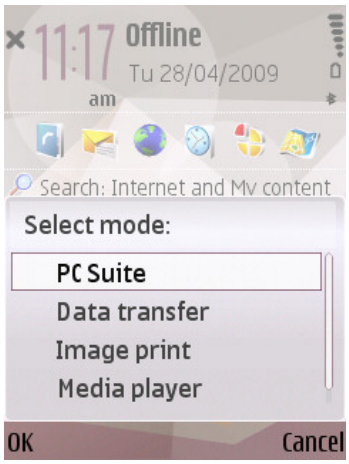

Figure 2 - Mobile phone's select mode

- Step 2
  Open the Nokia PC Suite installed in the personal computer. Then select the option *Install applications* (See Figure 3).

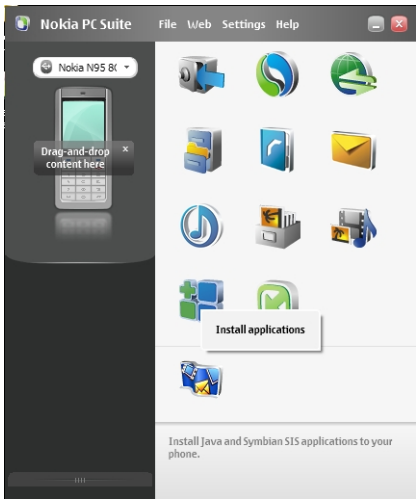

Figure 3 - Nokia PC Suite main window

- Step 3
  The Application Installer is shown, on the left side of the window it appears the personal computer's browser and on the right side it appears the mobile phone's browser. On the left side search and select the T7.2 MINAmI application's .sisx file and on the right side select Phone memory in order to install the Symbian application

there. With the corresponding .sisx file selected, click on the install arrow in order to start the installation on the phone's memory (See Figure 4).

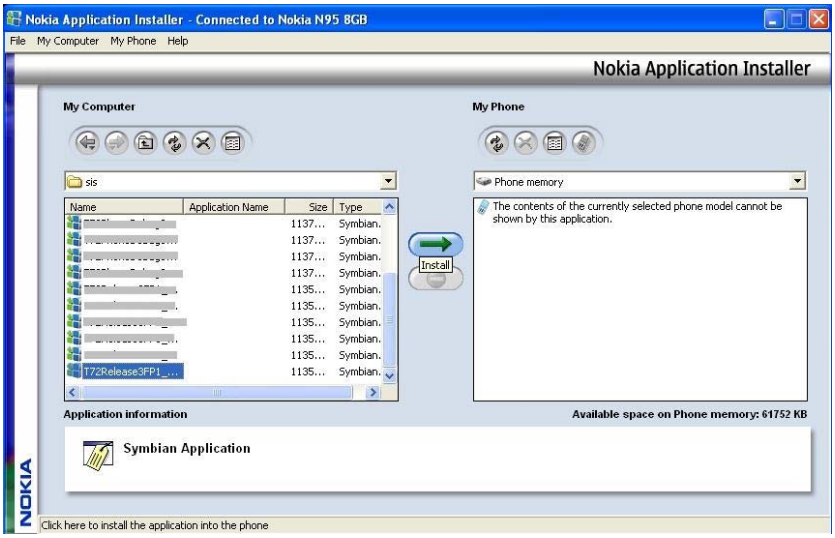

Figure 4 - Nokia Application Installer

3.2.2 Option 2: Windows Explorer's Nokia Phone Browser

- Step 1
  Plug the mobile device in the USB port of the personal computer. In a few seconds a menu is visible in the mobile device, then select that it's going to be used the PC Suite (See Figure 5).

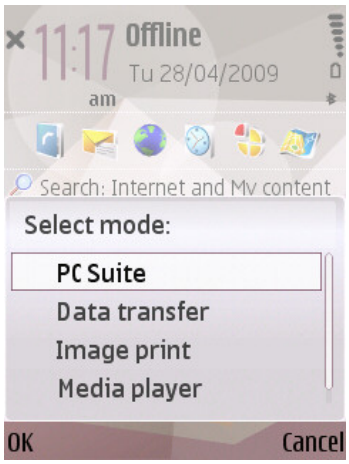

Figure 5 - Mobile phone's select mode

- Step 2
  Open a Windows Explorer. On the left side it appears the personal computer's browser. When selecting on the left side the Nokia Phone Browser directory, on the right side of the explorer it appears the mobile phone's browser (See Figure 6).

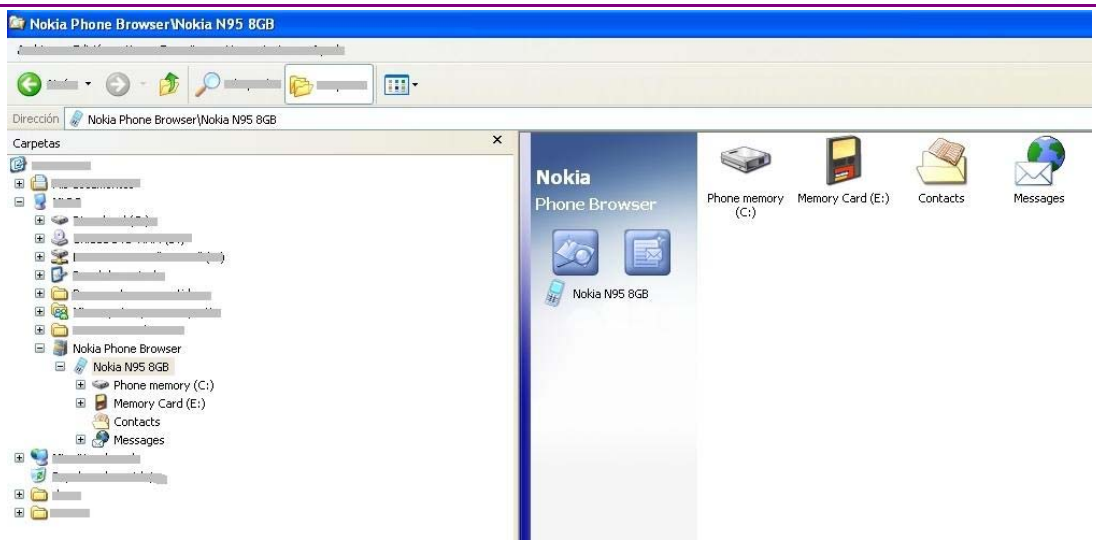

Figure 6 - Nokia Phone Browser

- Step 3
  Search the T7.2 MINAmI application's .sisx file placed in the personal computer and copy it into the Phone memory of the mobile phone.

- Step 4
  Browse into the Phone memory and select the Symbian application copied in the mobile device. Make double click on it; it'll ask for a confirmation, say yes and the installation on the phone's memory will start (See Figure 7).

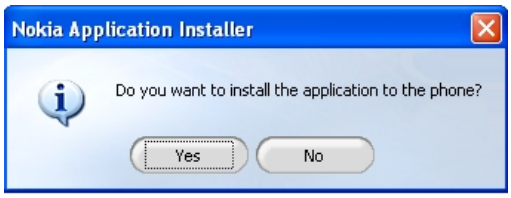

Figure 7 - Install confirmation

3.2.3 Update application

If it's necessary to update the application installed version, just delete the application from the mobile device and follow again the steps specified above.

3.2.4 Installation test

Once the application is installed, it's now available in the Applications folder on the mobile device's menu. Click on MINAmI_T7_2 icon and if the first page of the application appears it means that the application was installed successfully.

3.3 Server

The installation of the Web server is out of project's scope in phase II. It has been used a TID test environment and server.

3.3.1 Environment specifications

The host name is *minami2* and it has the following characteristics:

- Microsoft Windows XP Service Pack 2.
- Java 2 SE Development Kit: JDK 6 Update 2.
- Web Server Apache Tomcat 6.0.14.
- Secure Protocol SSL.
- Logging utility Apache log4j library.
- T7.2 Web application deployed in the server.

3.3.2 Authentication and authorization

The mechanism used to authenticate and authorize users in the server is the *\apache-tomcat-6.0.14\conf\tomcat-users.xml* resource offers by the Web Server Apache Tomcat. The user's roles are specified in that file in the following way (See Figure 8):

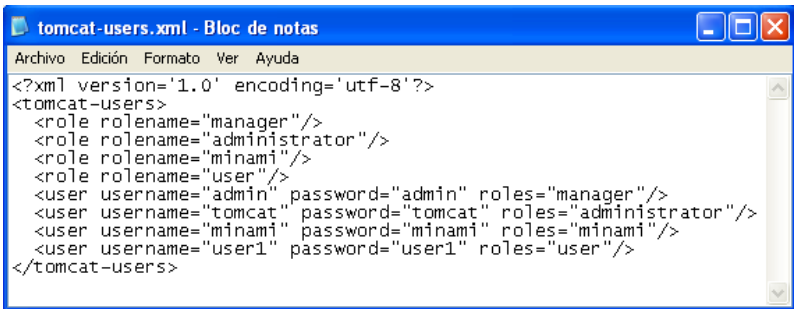

Figure 8 - Tomcat users

The T7.2 Health monitoring & Homecare demonstrator Web Server application is configure to authenticate and authorize the role *minami*, so *minami* it's the only user to have access to the T7.2 Web application.

3.3.3 Server availability

It must be performed the following test to ensure the server is working.

- Type in any PC's Web browser connected to Internet the following URL: https://minami.fp6.tid.es/DemostratorT72/data
- It's a test server; a certificate error is expected so pass around if possible.
- Then a pop-up window will ask for a login/password. If it's typed a wrong login/password the pop-up window will open again until it's typed the correct one.
- If the Web server is started up and the login/password is correct, the server must respond with a blank page (See Figure 9).

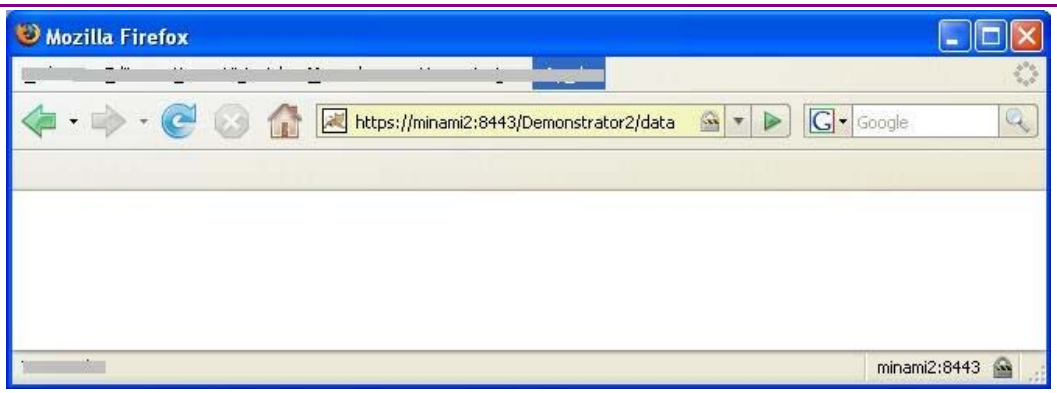

Figure 9 - Server response

Section 4 - User manual

This section explains how the users (patient, healthcare provider) shall use of the demonstrator system. The system consist of the components illustrated in Figure 10.

Figure 10 – EEG Logger system components

4.1 Sleep recording

The EEG Logger You just received is normally in so-called stand-by mode (red led blinks once in ten seconds). The EEG Logger detects automatically that you attach it on your forehead and start the recording (the led blinks once in a second). If the light is not blinking, place the EEG Logger on the Logger Base (see Figure 12) for some 10 seconds.

- Wash your face with soap. Do not use face-cream.
- Attach three electrodes to the EEG Logger. (First snap an electrode to the EEG Logger or the cable, only then remove the plastic shield from the adhesive.)

- Attach the EEG Logger on the forehead. (The orange cable on low left.) The lower edges of the electrodes shall be about 1-2 cm above eyebrows. The EEG Logger shall be horizontally centered. See Figure 11.
- Ensure good contact by pressing the edges of the electrodes with fingertips.
- Attach the third electrode (on the tip of the cable) on the temple on the eye-line.
- The red LED on the top blinks once in a second to show that measurement is going on.
- (It may take up to 10 – 15 minutes for the measurement to start, depending how long it takes for the electrode contact to stabilize.)
- Go to bed and sleep normally.
- In the morning, detach the EEG Logger. (The measurement will go on and the LED keeps blinking until 10 hours from the start of the recording, even if the EEG Logger is detached.)
- Detach and dispose the electrodes.
- Clean the adhesive residue from your forehead using a disposable fingernail polish remover pad.

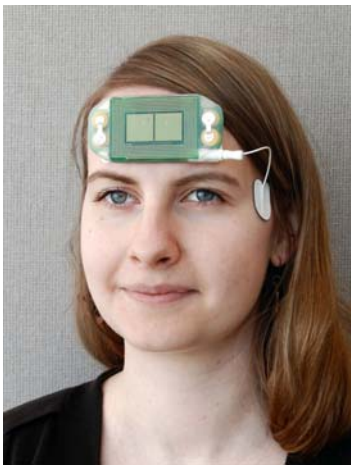

Figure 11 – Placing the EEG Logger for sleep recording

Note The skin under the electrodes may be slightly reddish. This will disappear in few hours.

4.2 Data transmission

Environmental needs:

- Internet connection (through GRPS or Wi-Fi access point).
- Mobile device with signed MINAmI T7.2 application installed.

Procedure:

- Power up the Logger Base. (‘Power’ LED is illuminated continuously, ’Charging’ LED blinks once in ten seconds.)
- Place the EEG Logger on the Logger Base precisely as in shown in Figure 12. (It does not matter if the LED in the EEG Logger is blinking or not.) Data readout from EEG Logger to Logger Base starts automatically and takes about 15 – 20 minutes.

Figure 12 – Placing the EEG Logger on Logger Base for data transmission

- Once 'Connect Phone' LED starts blinking (after about 15 – 20 minutes), data is ready to be transmitted to medical server.
- T7.2 MINAmI application is available in the Applications folder on the mobile device's menu (see Figure 13). Activate the MINAmI mobile application by selecting the appropriate icon.

4.3 Mobile device application

Environmental needs:

- Sleep logger and Reader & Charger prototype to test functionalities.
- Bluetooth for communications.
- A running HTTP web server for communications.
- Internet connection (through GRPS or Wi-Fi access point).
- Mobile device with signed MINAmI T7.2 application installed.

4.3.1 Open T7.2 application

T7.2 MINAmI application is available in the Applications folder on the mobile device's menu (See Figure 13).

Figure 13 - Application T7.2

4.3.2 Start the application

When the user runs the MINAmI_T7_2 application, a dialog is displayed to select the access point to be used in data transfer to server (See Figure 14).

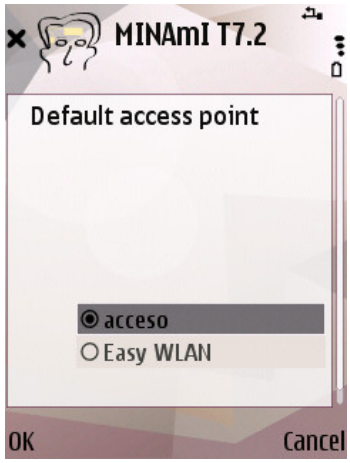

Figure 14 – Access Point Selection

If there isn't any configured data logger, the application starts a Bluetooth device discovery procedure:

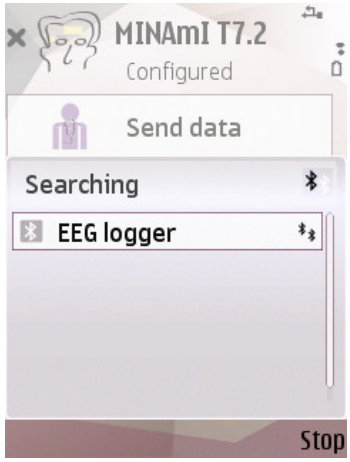

Figure 15 – Searching data logger

The user can cancel this procedure or select one of the found devices, in this case the configuration with the selected data logger is established. The status of the configuration (Configured/Not Configured) is set in the upper part of the main view, as follows:

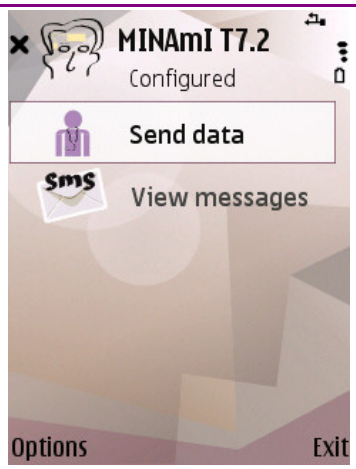

Figure 16 – MINAmI T7.2 main window

The main window displays two items: *Send data* and *View messages*. Following each item is described in detail.

4.3.3 Options

In the bottom left part of the main view there is a soft key labelled “Options”. Clicking this key a menu is presented with the following actions (See Figure 17): *Select, Configure*, *Help* and *Exit*.

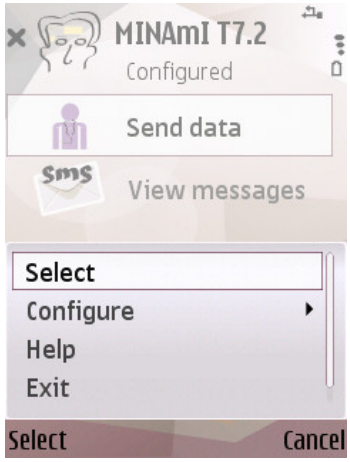

Figure 17 - Options

The user can interact with the application through this menu. The user can select one action or cancel the menu showing the main view again. Following each action is described in detail.

4.3.3.1 Select

When clicking ‘Select’ option, different actions take place according to the selected item.

- *Send data:*

  In case of “Send data”, the application verify if data from data logger is stored in mobile. In other case, it establishes a Bluetooth connection with the configured data logger. If any data logger is configured, it displays an information note to the user.

As soon as the Bluetooth connection is established, the application receives data from data logger (See Figure 18).

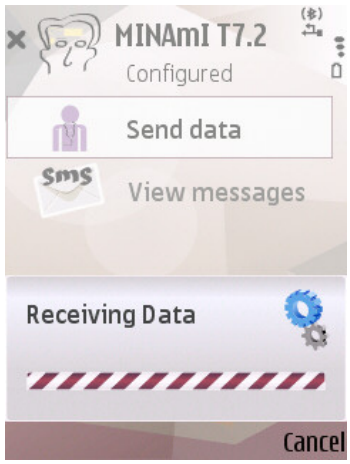

Figure 18 – Receiving data from data logger

When data reception ends, the transfer data process starts (See Figure 19).
The server settings have to be configured and the access point selected (See 4.3.5).

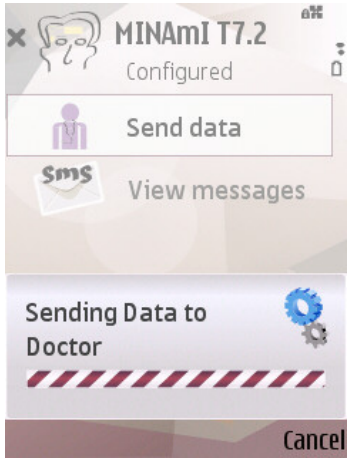

Figure 19 – Sending data to server

Action result is displayed on screen:

In case data logger was stored in mobile when clicking the 'Select' option, the user decides if he wants to send this stored data to server or remove old data and establishes a connection with data logger and receive new data (See Figure 20 and Figure 21).

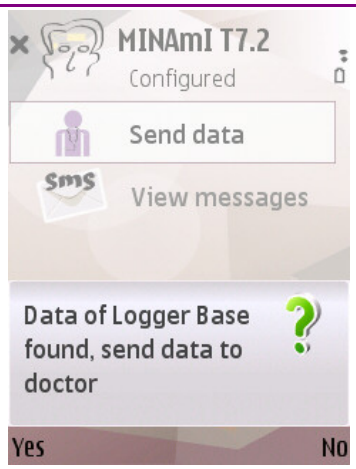

Figure 20 – Data stored in mobile phone

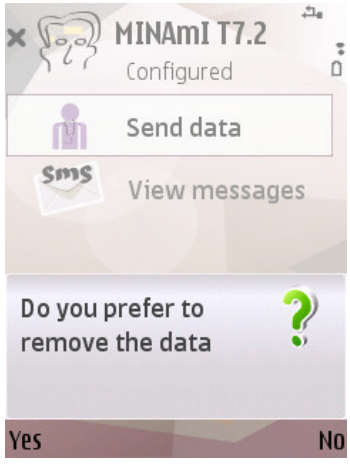

Figure 21 – Confirmation to remove data

- *View message:*

  This screen shows a list of historical messages that the server (the physician) sends to the patient (See Figure 22). The left soft key 'Options' presents a menu to select the marked message and read its content or Back to main view.

Figure 22 – Sms view

4.3.3.2 Configure

If the user selects this option a sub-menu is displayed (See Figure 23). The options here correspond to: *Logger and Server.*

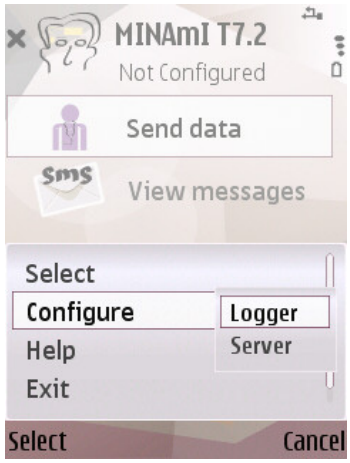

Figure 23 - Configure options

- Logger
  When selecting this option a new procedure for searching data loggers starts (See Figure 15).

- Server
  When selecting this option some setups regarding the web server are introduced here: URL, login, password (See Figure 24). Further information in 4.3.5.

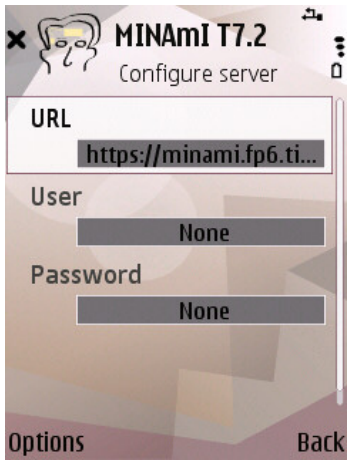

Figure 24 - Server settings

4.3.3.3 Help

This option gives information about the software version of the MINAmI_T7_2 application.

4.3.3.4 Exit

If the user selects this option, it has the same behaviour as the right soft key in the main view of the application; the application is closed showing the Applications menu again of the mobile device.

4.3.4 Exit

In the bottom right part of the main view there is a soft key labelled “Exit”. Clicking this key the application is closed asking for a confirmation (See Figure 25) and showing the Applications menu again of the mobile device.

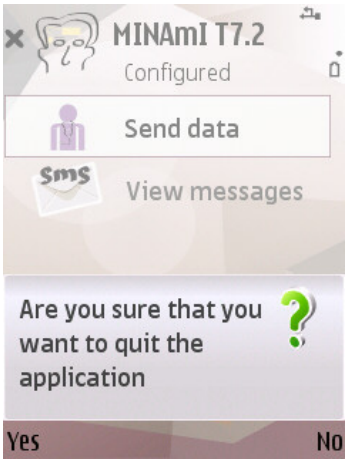

Figure 25 - Exit confirmation

4.3.5 Options (Server Configuration)

When selecting the soft key ‘Options’ in Server Configuration view (See Figure 24), the menu displays the following actions: *Change, Test Configuration, Help and Exit* (See Figure 26).

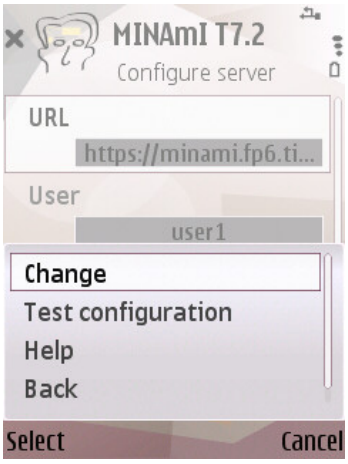

Figure 26 – Options menu in Server Configuration window

4.3.5.1 Change

When selecting this action, the user can change the value of the selected item.

The URL that must be typed to configure the server is: https://minami.fp6.tid.es/DemostratorT72/data. The login / password are (case sensitive): user1 / user1.

4.3.5.2 Test Configuration

This server configuration must be tested in order to authenticate and authorize the user selecting this option. The server response is displayed on screen, as follows

Figure 27 – Server response to Test Configuration

4.3.5.3 Help

Not implemented.

4.3.5.4 Back

Selecting this option, the application comes back to main view (See Figure 16).

4.3.6 Back

Clicking the soft key labelled 'Back', main view is activated.

4.4 Server

The Web server is hosted in a TID's test server and stores the MINAmI T7.2 Web application. The Web application receives in chunks the file stored in the mobile phone memory and stores it in the structure of the server.

4.4.1 Login

To access to the website, the user can navigate to the following URL: *https://minami.fp6.tid.es/DemonstratorT72/Login.action* .This will open a secured connexion to the web interface (Figure 28). The interface requires login and password.

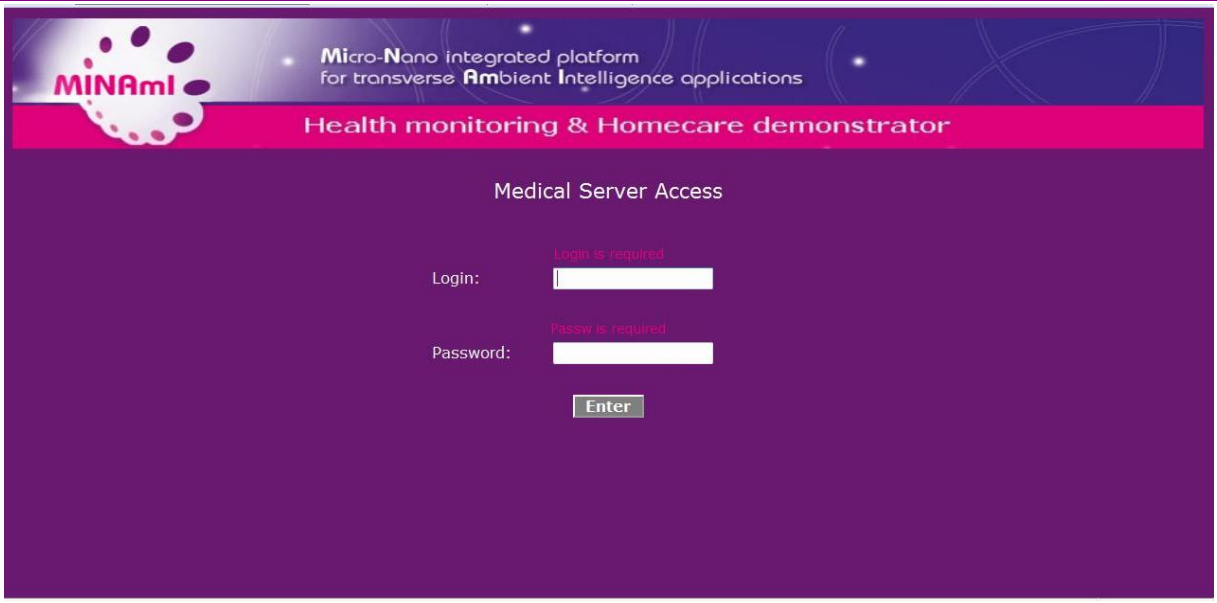

Figure 28 - Login action

If login and password are right, the user can access to registered patient information. The options are: select a patient to get further information, register a new patient or update data (Figure 29).

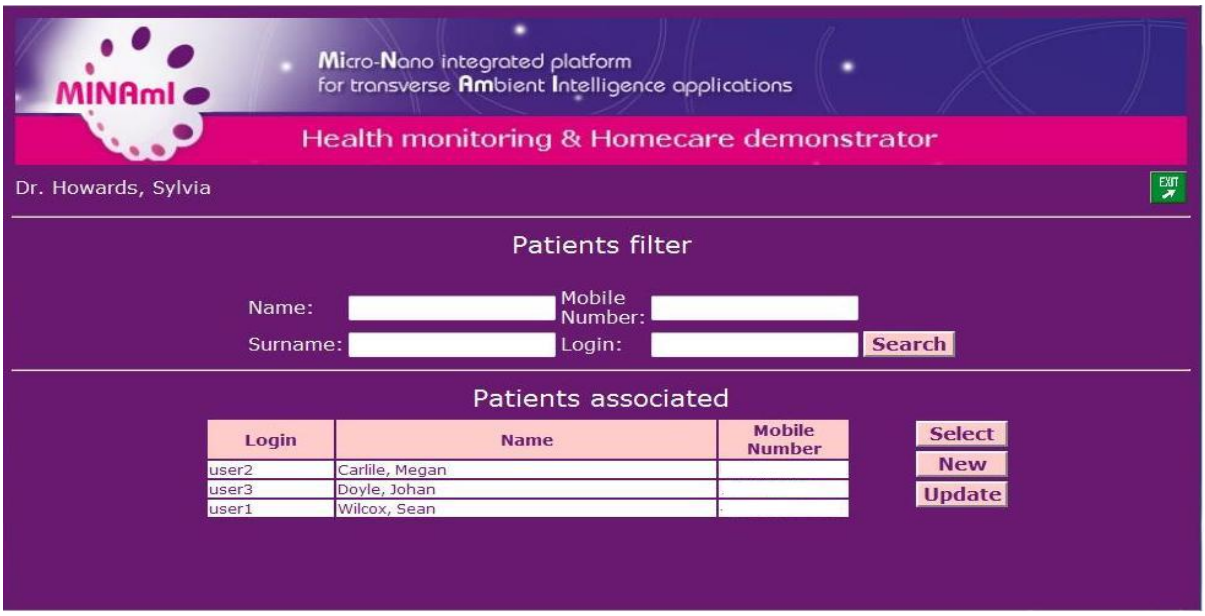

Figure 29 - Registered patient information

4.4.2 Patient data

The user can update any personal data related to registered patients (Figure 30).

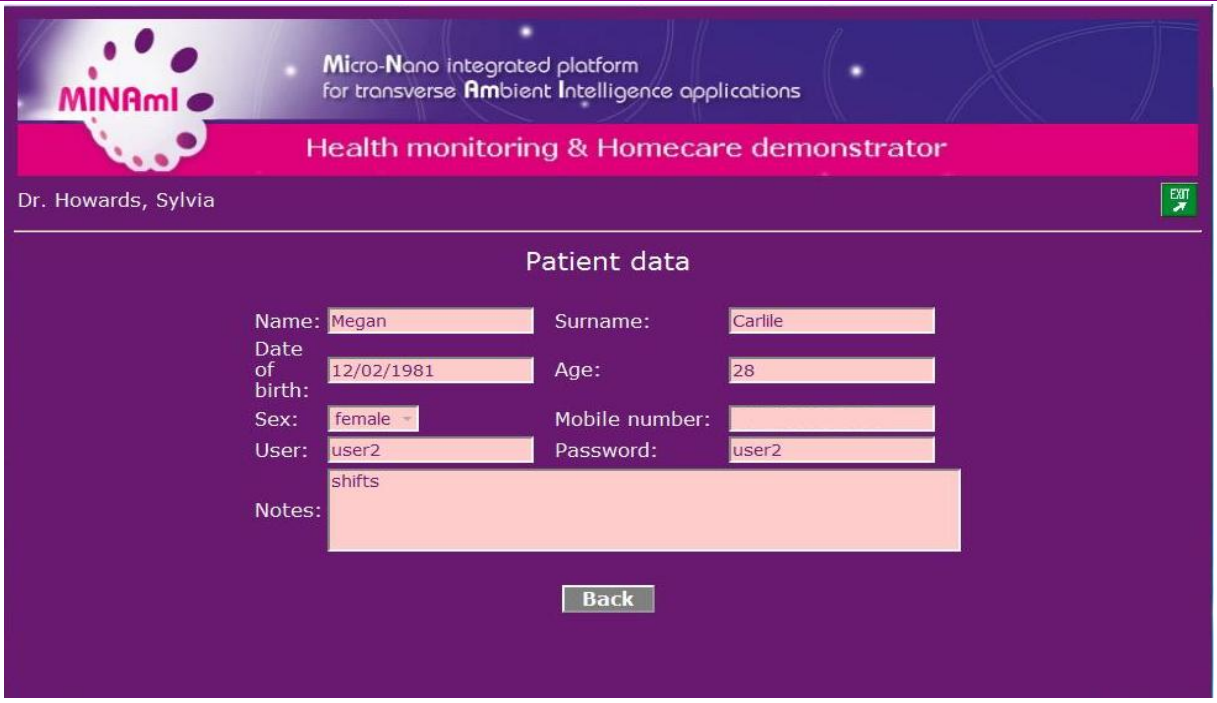

Figure 30 - Patient personal data information

In the same way, the files received from each patient are available to the user (Figure 31 and Figure 31).

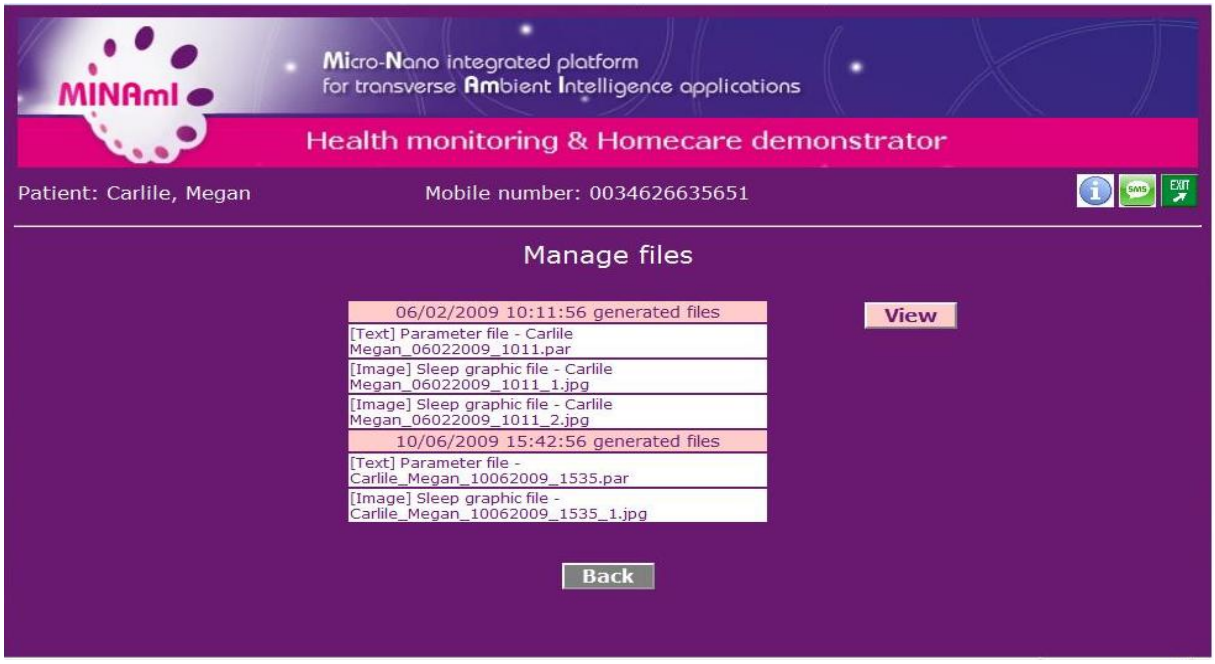

Figure 31- Files related to a registered patient

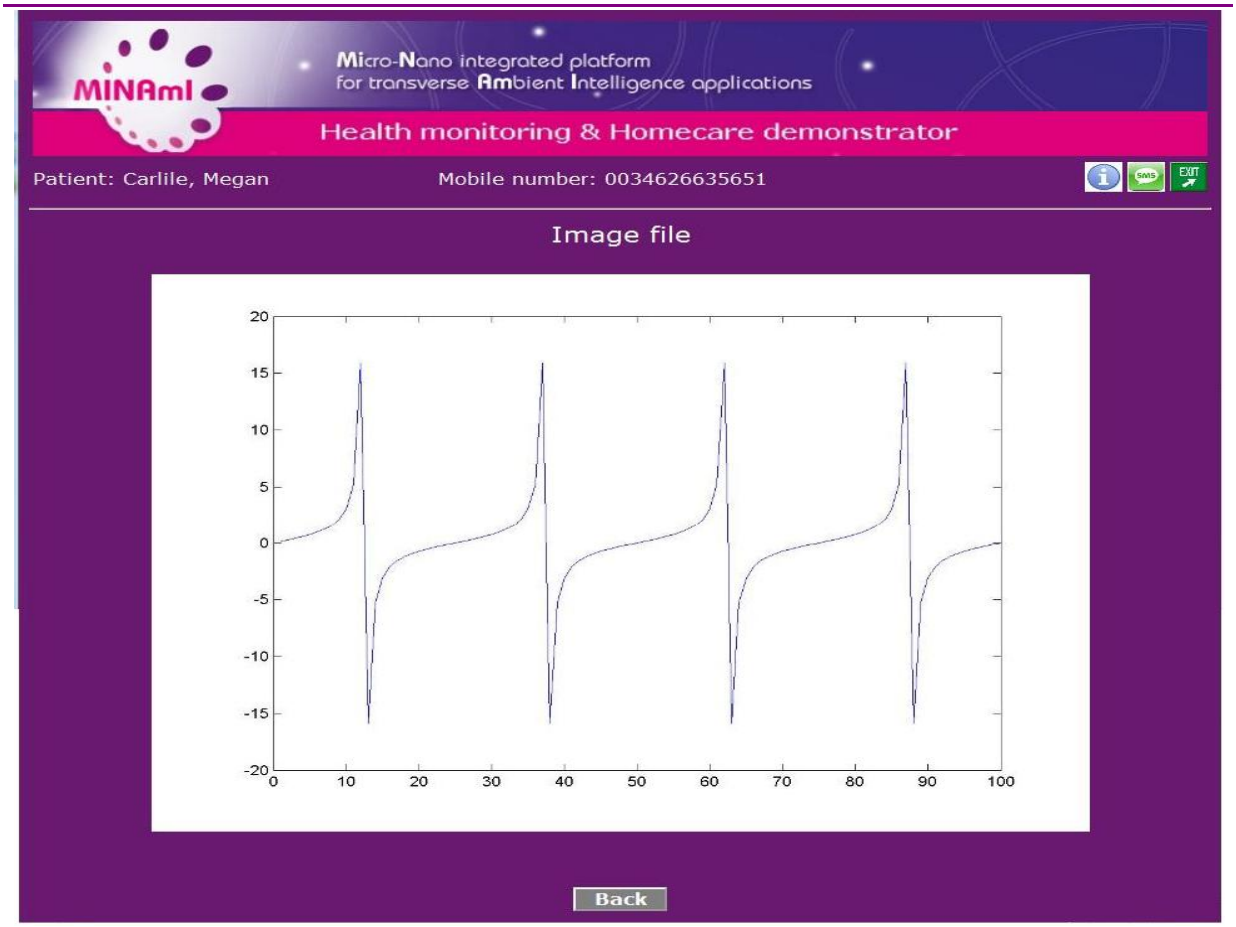

Figure 32 - Image related to patient data

The user can send SMS to registered patients to inform about results and medical appointments (Figure 33).

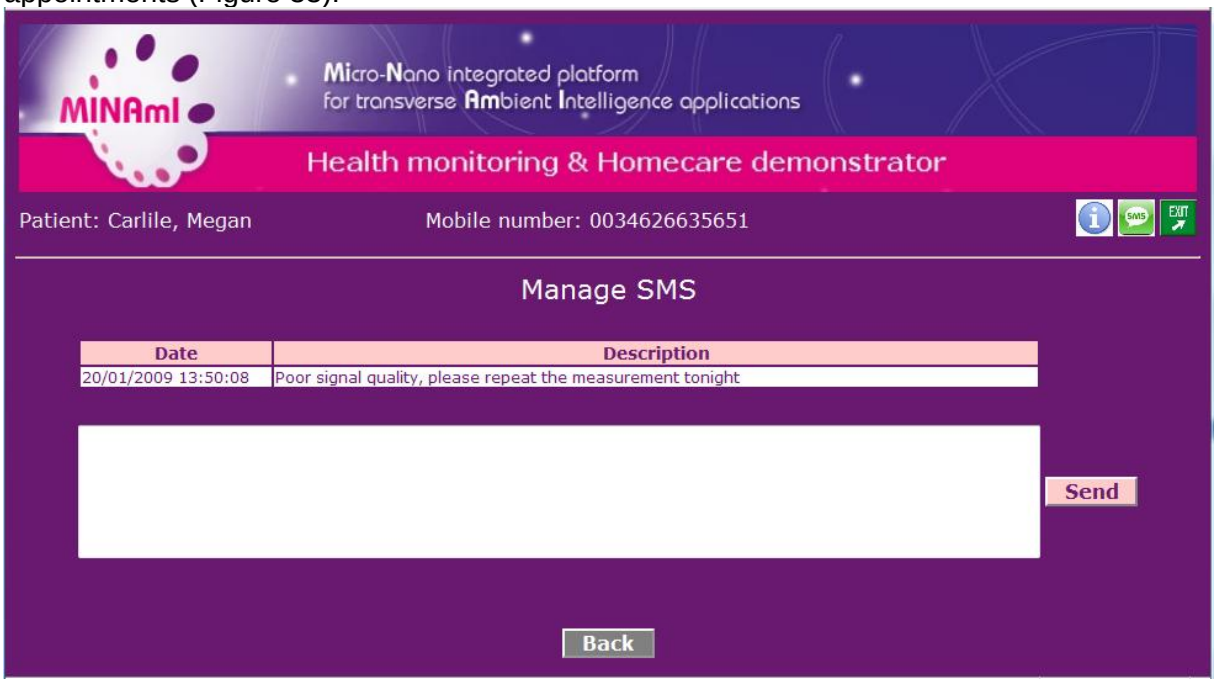

Figure 33 - SMS sent to patients

Section 5 - Test Report

5.1 Verification

Document *MINAmI Frontal EEG Logger Verification Protocol* in Annex 1 includes test cases with test results for verifying the requirements as specified in the following documents:

- D7.12 Final demonstrator requirements
- D7.13 Functional description of the final demonstrators
- D7.14 Test & validation plan for the final set of demonstrators

The requirements and respective test results are also summarized below. Lithium battery test results can be found in D4.13.

In summary, the demonstrator has fulfilled the requirements set for it and has successfully passed the respective test cases. Having met the technical goals, the demonstrator has also achieved the main goal, which was to develop a functional system for user evaluation.

EEG Logger

Requirement TAG	Description	Status	Comments
EEG-LOG-001	No user-operated switches or controls	OK	
EEG-LOG-002	Disinfection between users	OK	
EEG-LOG-003	Sterile skin contact	OK	
EEG-LOG-004	Data readout without battery power	OK	Batteries recharged automatically when necessary
EEG-LOG-005	One recording session shall last overnight	OK	
EEG-LOG-006	The logger shall not disturb patient's sleep	OK	Dimensions 40x90 mm, required 40x60 Weight 60 g, required 50g
EEG-LOG-007	Data downloading time	OK	Readout 15 min, < 30 min required
EEG-LOG-008	The data shall be time-stamped	OK	Download time as surrogate
EEG-LOG-009	The non-disposable logger shall be economical to use	OK	

Logger Base

Requirement TAG	Description	Status	Comments
EEG-RDR-001	No user-operable controls in the data reader	OK	
EEG-RDR-002	Unambiguous pairing of reader and tag	OK	
EEG-RDR-003	Data download shall initiate automatically	OK	
EEG-RDR-004	Data download shall terminate automatically	OK	

EEG-CHR-001	Extreme simplicity of use	OK	
EEG-CHR-002	No user-operable controls in the battery charger	OK	

Mobile application

Requirement TAG	Description	Status	Comments
EEG-MOB-001	Data transmission vehicle	OK	
EEG-MOB-002	User interface	OK	
EEG-MOB-003	Logger data readout	OK	Manual start required
EEG-MOB-004	Logger data transmission	OK	Message from expired certificate - requires manual confirmation
EEG-MOB-005	Notification reception	OK	
EEG-MOB-006	Secure communications	OK	

Medical Server and Sleep Analyzer

Requirement TAG	Description	Status	Comments
EEG-MDS-001	Mobile phone mediator	OK	
EEG-MDS-002	Medical server purpose	OK	
EEG-MDS-003	Patient notifications	OK	
EEG-MDS-004	Physician interface	OK	
EEG-MDS-005	Services composition	OK	
EEG-MDS-006	Patient notifications	OK	
EEG-MDS-007	User identification	OK	
EEG-MDS-008	Data protection legislation	OK	
EEG-ANL-003	Analysis algorithm interface	OK	

Test cases

The test cases to be tested appear in the document in D7.14 *Test & Validation plan for the final set of demonstrators*.

Test case TAG	Description	Status	Comments
TC_T72_01	Nightly logger recording	OK	
TC_T72_02	Logger reading & recharging	OK	
TC_T72_03	Observational test of the system	OK	
TC_T72_04	Configure mobile application	OK	
TC_T72_05	Transfer data to server	OK	
TC_T72_06	Visualize data	OK	

TC_T72_07	View messages and patient notification	OK	

5.2 Algorithm performance

The developed EEG analysis algorithms and their validation have been described in a public document:

Automatic Sleep Scoring from Frontal Electroencephalogram
Sipponen Sini
Master's thesis, Helsinki university of Technology, 2009

"The overall agreement between the four-stage automatic scoring and manual scoring was 79.1% (κ = 0:67). The values were at the level of typical inter-scorer agreement. Prediction probability value of Entropy™ was 0.89. The sensitivity and positive predictive values were 70% and 74% for wakefulness, 59% and 86% for REM sleep, 87% and 79% for light sleep, and 86% and 81% for slow wave sleep, respectively. The performance of the sleep-scoring algorithm was equivalent to similar developments reported in literature."

The key findings have also been published in a conference poster and abstract:

Wireless Forehead EEG Logger And Automatic Sleep Stage Scoring
Virtanen J, Sipponen S, Lapinlampi P, Paraschiv-Ionescu A, Lamy J Salmi T, Meriläinen P
SLEEP, Volume 32, Abstract Supplement, 2009, A378

5.3 User Evaluation

5.3.1 Introduction

The sleep quality analysis demonstrator was evaluated in August 2009 with five test users. The users were GE employees as this kind of a prototype medical device could not be put to consumer evaluations. The objective of the evaluations was to get preliminary feedback on user acceptance of the concept as well as to test the technical functionality of the logger and the analysis software.

The user evaluation was organised in cooperation by GE and VTT. GE took care of the technical setup and user support, user guidance and sleep analysis. VTT took care of designing the questionnaires, interviewing the users and analysing the results. In addition VTT researchers acted as pilot users and carried out expert usability evaluation of the prototype.

5.3.2 Participants

The logger was evaluated with five voluntary users, recruited from GE staff, however, not people involved in sleep quality research. The users had personal interest towards the study. Four of them had technical background. Two of the five test users were women and three were men. The participants' ages varied between 33 and 57 years. According to their own descriptions, four of them usually sleep well and one never sleeps well. Four of the five participants are interested in trying out novel technology whereas one is interested in technology only if the technology is of help. The test users are presented in the Table 2.

Participant #	Gender	Age yrs.	Sleeping habits	Attitude towards technology
#1	Female	55	Usually sleeps well	Is interested in trying out novel technology.
#2	Male	56	Usually sleeps well	Is interested in technology only if the technology of help.
#3	Male	57	Usually sleeps well	Is interested in trying out novel technology.
#4	Female	36	Usually sleeps well	Is interested in trying out novel technology.
#5	Male	33	Never sleeps well	Is interested in trying out novel technology.

Table 2 – Background information of the test users.

5.3.3 Technical setup of the demonstrator

GE Healthcare has developed a Sleep Quality Analysis system as one of the seven demonstrators of MINAmI research project. The system is intended for home monitoring of sleep disorders.

The tested device was composed of an EEG Logger, a Logger Base for data readout and battery recharging, and a mobile phone for data transmission. The test device was used in home environment and no clinical decisions were made based on the test results.

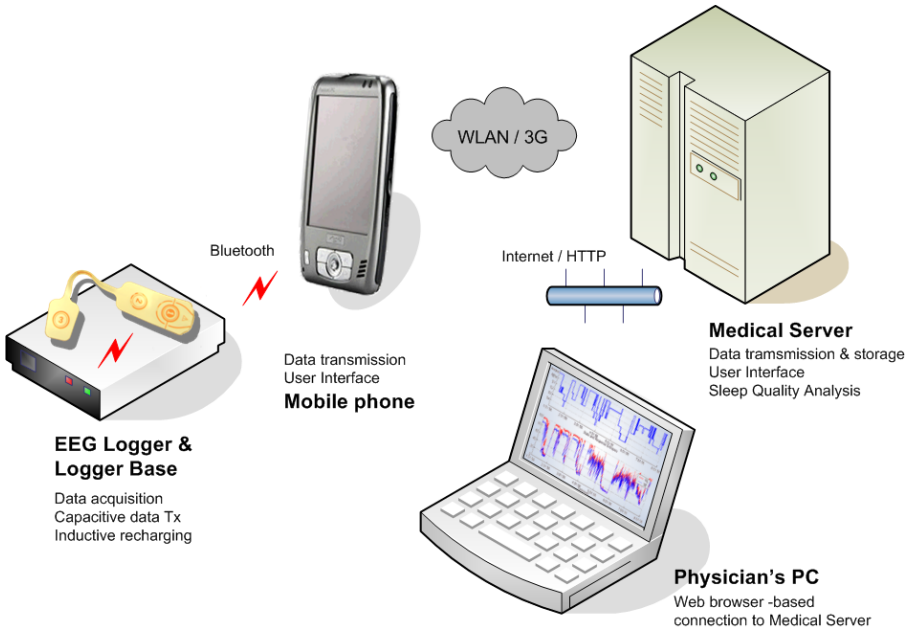

Figure 34 – A schematic diagram of the system under test

In the basic form, the user uses the EEG Logger for collecting EEG and acceleration signal overnight and sends the data for automatic analysis using Logger Base and mobile phone. The system enables repeated measurements and provides feedback between recording sessions.

The user initiates data logging in the evening by attaching the *Logger* on his/her forehead using adhesive electrodes. For data readout from the logger memory in the morning, the user puts the *Logger* on the *Logger Base*, which automatically performs data readout and recharges the logger batteries. The *Mobile Phone* is used to read the data from the base via Bluetooth and sending the data to Medical Server via 3G-connection. The Medical Server executes automatic analysis, provides user interface for the physician, and enables messaging with the patient's mobile phone.

The user instructions applied in the test were substantially identical as those presented earlier in this document.

Figure 35 – EEG Logger system components. The logger in the photo is an updated version. The logger that was used in the user evaluation is shown in Figure 36.

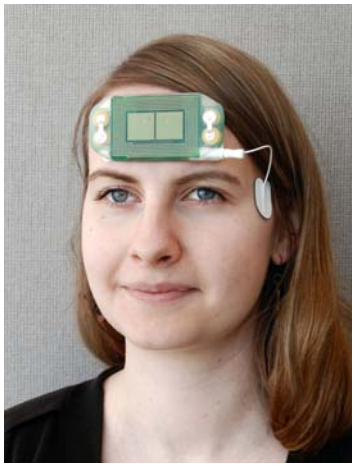

Figure 36 – Placing the EEG Logger for sleep recording

5.3.4 Evaluation procedure

Before the user evaluations, two VTT researchers carried out pilot evaluation with the logger in July 2009. The aim was to pilot the user guide, pilot the questionnaires and test the functionality of the system. The pilot users used the logger overnight and downloaded and transferred the data in the morning. They also filled in the questionnaires to test if the questions were feasible.

The user evaluation took place during August 2009. Before the actual test nights there was a common meeting with the test users and researchers at GE. The users were informed about the study and the logger and how it should be used. Each participant filled in a background questionnaire that studied expectations and motivations. They also signed a research permission. Also the test and interview schedule was agreed.

Each test user used the logger overnight. In the next morning the user filled in a questionnaire about how (s)he slept and how the logger felt. The user took the logger with him/her to the working place where (s)he uploaded logged data to the logger phase. Finally the user transferred the data from the logger base to a mobile phone that was part of the test equipment and used the MINAmI application on the phone to send the data to the remote server to be analysed. After carrying out the data transfer, the user continued filling in the questionnaire concerning user acceptance of uploading.

The next day after the data transfer, the user had an appointment with a sleep analysis expert, who showed and explained to the user the results of the analysis. The user got the sleep analysis with him/her on paper.

The final interview was made by phone. The focus of the interview was on user acceptance of the system. The final interview was based on the test user feedback only, for privacy reasons the evaluator did not have access to the recorded data or the sleep analysis.

VTT researchers analysed the evaluation results and produced a draft evaluation report. These results were presented to GE people in a workshop. In addition to the project personnel, two test users, the medical supervisor of the evaluation and two clinicians participated in the workshop. The workshop participants discussed the results and proposed development ideas.

5.3.5 Results of the expert evaluation

The expert evaluations revealed some issues in the user guide to be refined. The evaluations also revealed some usability problems in the logger and logger base. These problems were fixed before the user evaluations as described in the following:

In the user guide, the meaning of the blinking and then continuously illuminated LED in the logger base under “Connect phone” was specified:
“Blinking ‘Connect Phone’ tells that data is ready to be transmitted to medical server for analysis. (Once the data has been transmitted, the LED is illuminated continuously.)”

Equally, a notice was added to emphasize that the logger should not be removed from the base when recharging was going on:
“IMPORTANT: Do not remove the logger from the base after the downloading to facilitate battery charging. Each time you replace the logger on the base, the downloading starts from the beginning. During downloading, the Charging led will be off and on by turns. The continuous charging starts only after downloading has been completed.”

We also added instructions in case the transmission gets stuck:

"If the transmission gets stuck, exit the MINAmI mobile application, remove the Logger from the Base and reset the Base by plugging it off and on. Then put the Logger back on the Base and start from 6. again."

Software changes were required to use the error LED only for actual errors, not to indicate that the logger battery needed recharging during the data transfer.

The SMS acknowledgement message "Night recording correctly received, waiting for doctor analysis" was suggested to be more specific. It would be beneficial to check that the recording is technically valid, long enough. In that case it might be good to give feedback on the length as well, e.g. "Sleep data for 8,5 hours received, waiting for doctor analysis".

The correct position of the logger on the top of the logger base was marked with a sticker to ease positioning the logger correctly.

5.3.6 Results of the user evaluation

5.3.6.1 Sleep monitoring

Ease of use of the sleep logger

Usage of the sleep logger was described "straightforward" (#3), "easier than I thought" (#5) and "exciting" (#1). Generally, setting up the sleep logger in the evening went smoothly and without bigger problems. It was described "quick" (#1), "effortless" (#2) and "plug and play" (#5). One user (#3) pointed out that he set the temple electrode by mistake on the right side of his forehead. This was firstly because he is right handed and instinctively put the electrode to the right side, and secondly since one looks himself in the mirror as mirror image even if the photo in the instructions shows the electrode on the left side. (Evaluator comment: this could be fixed if the correct position is marked with up/down rather than left/right).

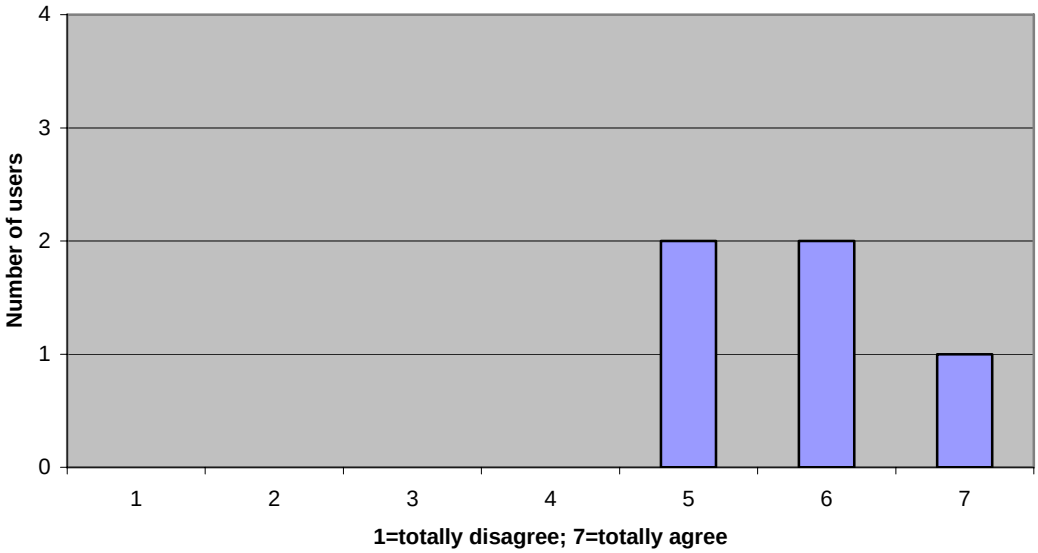

Figure 37 – Taking the logger into use was felt quite easy

One user (#4) mentioned that it took some time before the logger started collecting data. She tried to press the electrodes against her forehead thinking that this would help to activate the contact. She pointed out that it should be mentioned in the instructions that it takes a while before the LED starts blinking and the connection is actually activated. (Comment from final workshop: The start up may take up to 10 minutes. The user guide was updated with this information after the two first test users.)

Detaching the logger in the morning was found easy and straightforward. No problems occurred. One user (#5) described: "Detaching was easy since I didn't have to switch off anything." Regardless, since the red LED was still blinking in the morning one user (#2) was uncertain if he could begin with the data transfer. (Evaluator comment: This should be instructed in the user guide).

Sleep quality

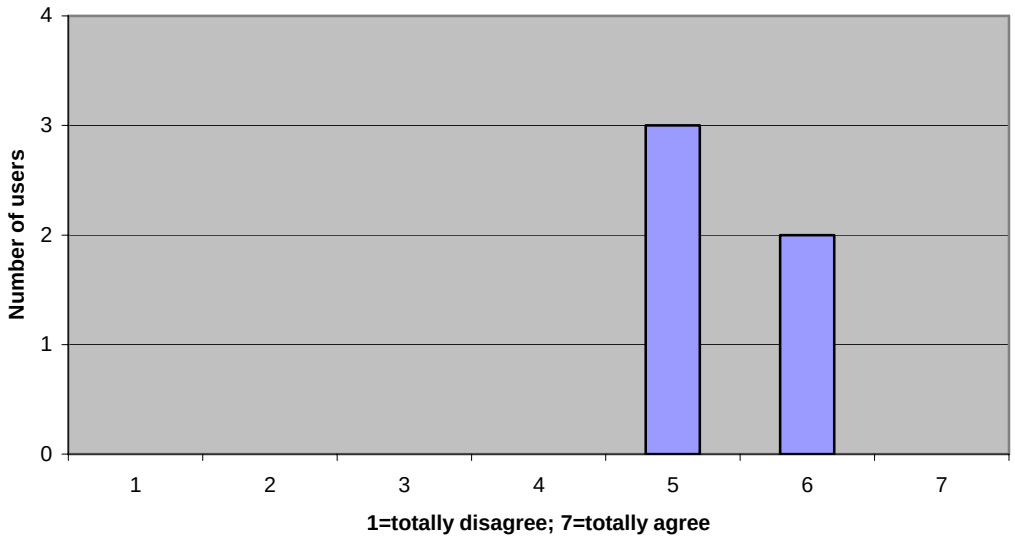

Figure 38 – The users felt that the logger did not disturb their sleep much

As a whole, the users slept well with the sleep logger. However, they did have some presuppositions of not falling easy to sleep with the logger and one user (#4) described that she almost panicked before going to bed. She was afraid that she may not easily fall asleep with the logger. One user (#3) said that at first it felt weird to go to sleep with a logger on the forehead. Anyhow, he slept well. One user described: "I forgot the existence of the logger in a few minutes" (#2).

The users would be ready to use the sleep logger for several nights. One user (#5) stated: "I could imagine using the logger even for a week."

Four of the five users felt that the existence of the logger did not disturb or harm their sleeping. One user (#1), who according to her own experience, did not sleep well, estimated that 10% of the restlessness of her sleep was due to the sleep logger and 90% since she had a period of restless sleep going on. One user (#2) also mentioned that he had to adjust the pillow so that the logger did not press against his head. One user (#5) pointed out that the blinking red LED of the logger did not disturb him or others sleeping in the same room.

Based on the users' own estimation, four of the five users had no difference in the amount of sleep during the test night compared to their normal night. One user (#4) normally sleeps 8-10 hours a night and during the test night she slept 6-8 hours.

Comfort of use

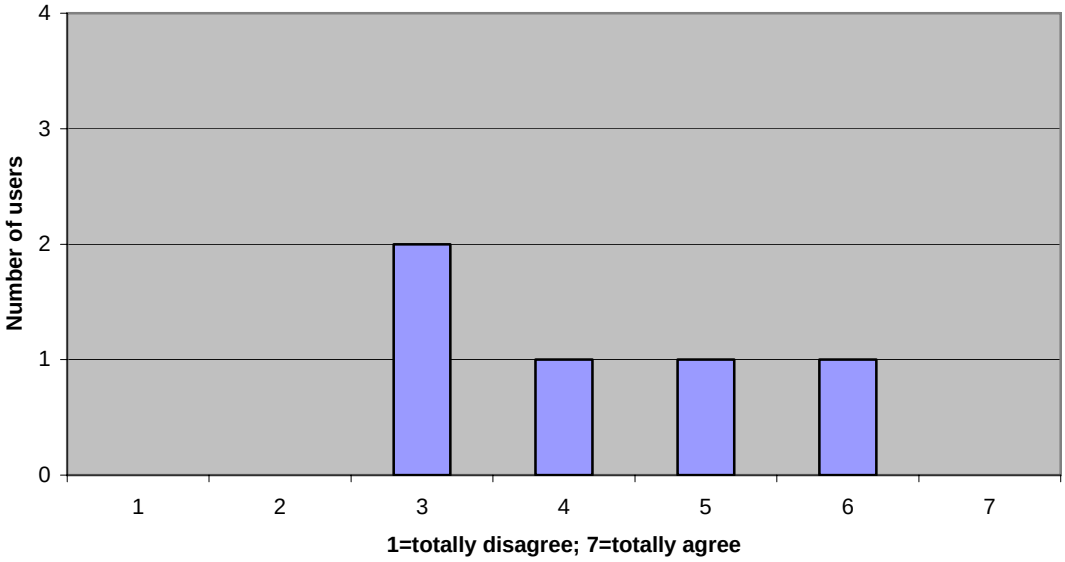

Figure 39 – The logger felt more comfortable than the users expected

The sleep logger was described "surprisingly comfortable" (#4) and "more unnoticeable than I thought" (#5). However, the logger was also claimed to be "big" (#1), "heavy" (#1) and "not comfortable" (#3). It was hoped that the device +would be smaller, lighter and more elastic. It was commented that the logger should not be any bigger sideways not to disturb sleeping. One user (#4) suffered from itching on her forehead during the night because of the adhesives. Nonetheless, as she removed the adhesives in the morning, the itching ended and did not bother her any more during the next day. She suggested researching if there were diverse types of clues that would not cause itching. (Comment from the final workshop: there are actually various alternatives available).

The temple electrode was suggested to be smaller since now some hair was easily left under the electrode (#2). The connecting point between the logger and the temple connectors' wire was described "robust" (#5). In the final product the joint was proposed to be somehow protected (#5). One user (#2) suggested that the temple connector could be wireless and he also proposed a device where all the electrodes would be "a part of an integrated thing attached on the forehead". Accordingly, one user (#3) suggested that the logger would not be attached on the forehead but somewhere else. These comments highlight that that users may have not fully understood the measuring principle, e.g. that the eye movement monitoring needs to be ear the eye. It would be beneficial to describe these basic principles in the user guide.

The design of the logger was described "harsh" (#3). As such, the appearance may generate fears what the device is doing to one's brain during the night. It is not obvious that the device is just measuring and "not sending signals" (#4). However, the users did understand the fact

that the sleep logger is still a proto and they commented that the ergonomic issues were clearly not yet considered.

5.3.6.2 Data transfer

Data transfer was clearly the more challenging part of using the sleep logger. Table 1.5 illustrates the feedback that the users gave with the questionnaire right after they had carried out the data transfer.

Several users highlighted the need for the accurate placement of the logger on the logger base. The users wanted to be certain about the right location of the logger on the base station. It was also brought out that an accidental push may move the logger and thus interrupt the transfer if the logger is not firmly placed. A slot or a hole on the base station was suggested to help to place the logger correctly. A separate green LED light was suggested to indicate that the logger is connected and starts to transfer data.

Figure 40 – Placing the EEG logger on logger base for data transmission (left) and the labels on the base (right).

The LEDs were seen helpful but not considered informative enough. A small LCD display on the box was suggested to be useful to facilitate text information. A progress bar on the logger base was also proposed. Also, the LED colours should be considered more carefully. The red and orange LED colour gives the impression that something is wrong.

One user (#1) was confused since in the written instructions there was an inaccuracy about powering up the logger base. One user (#4) highlighted the importance of personal guidance before the test. She told that it was easier to use the devices when one has seen the usage before. Accordingly, the importance of the precise written instructions was brought out in several answers. It was mentioned that the stuck in the data transfer did not feel that bad since it was mentioned in the instructions that this may occur. It was found necessary that also exceptional cases are described in the instructions: “I feel confident as I know that this has happened before” (#4).

All except one of the test users read the instructions. One user (#3) mentioned that he never reads instruction manuals. So, he did not read the instructions and carried out the data

transfer trusting on his memory. He had to interrupt the data transfer because "it stuck looping". He did not know if this was due to his action or a technical problem.

Learnability of the system was seen high but the written instructions were seen very important role in the usage. The routine of use was assumed to come after one night of use (#1).

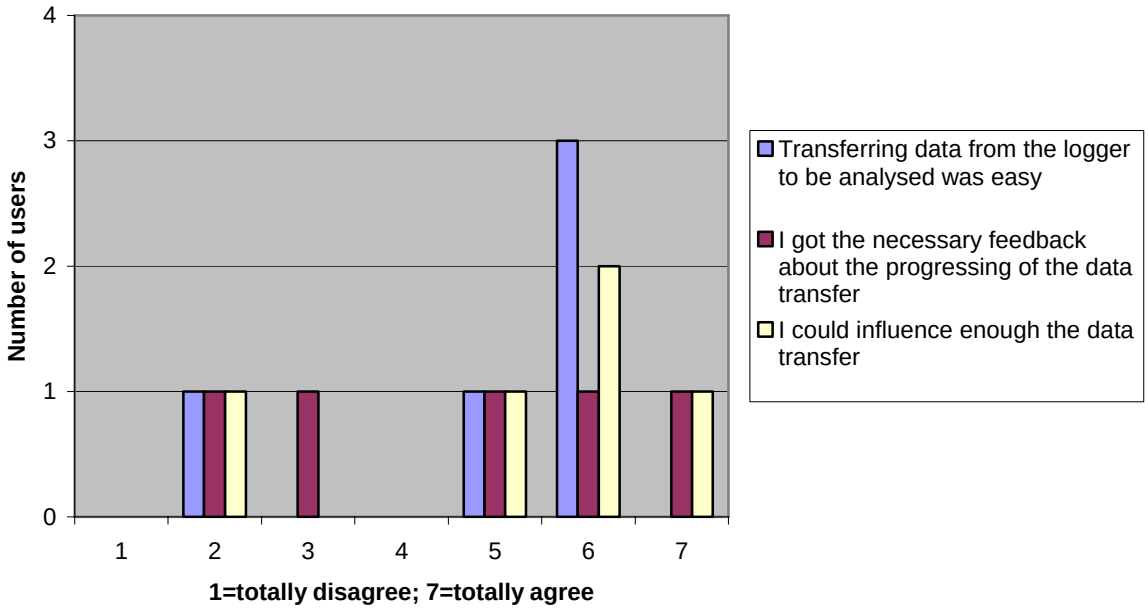

Figure 41 – User feedback of the data transfer

Problems occurred mainly in the data transfer between the logger base and the mobile phone. Almost all (4/5) test users told that data transfer was stuck. One user (#2) even had to call the technical support at GE to help and reset the system. The user told that if technical support would not have been available he would not have known what to do. In the following the users describe their expressions of data transfer:

> "The first data transfer did not succeed – it got stuck. I waited about an hour." (#1)
> "There was a real stuck situation with the phone." (#2)
> "I interrupted the data transfer and started again." (#3)
> "It did not succeed on the first try." (#4)
> "This was almost too easy since it was so automatic." (#5)

Two users (#1, #4) mentioned that the acknowledgement message did not arrive. One of them (#1) transferred the data again because she did not know if the first try was successful.

Despite the problems in data transfer, the users gave quite good grades to the ease of transferring the data. This may be due to the good user guide with which most users could solve the problem.

There were several phases in data transfer. This confused users. For example, one user (#2) was confused about the indication "Receiving data" when starting the data transfer with the mobile phone. He was confused as he thought that the mobile phone is sending data, not receiving.

Three of the five users (#2, #4, #5) were wondering why the mobile phone was needed. The phone was described “additional” (#4), “unnecessary” (#5) and “an intermediate grade” (#4). One user commented: “It felt pointless to transfer data several times” (#5). The sleep logger together with the logger base was seen adequate in the future.

Users had trust in data transfer. None of the test users had concerns regarding the reliability of the transfer. The sleep data as such was not felt confidential. Most of the users were familiar with data transfer and had some experience. This helped them to trust the transfer. They felt that a third party would have no use of the data. “It is not money related data or a doctor's certificate. (#2)”

5.3.6.3 Sleep analysis

The sleep analysis data consisting of graphs and the textual feedback (shown in Figures 1.5. and 1.6.) was explained privately to each test user by a sleep analysis expert. The sleep analysis supported and opened up many users’ assumptions about their sleeping. One user (#3) was especially interested in the information about awakenings in small hours. After hearing the sleep analysis he pieced together that the sleep is normally getting lighter towards morning. Knowing this he is no more worried and can now fall asleep again without worrying. Accordingly, one user was familiar with theory of sleeping and he was interested in seeing his own sleep analysis. He commented: “I have read about sleep cycles. The sleep analysis told me that there really are cycles in my sleep also” (#5).

In general, the participants saw the results reliable. It was commented e.g. “I have no reason to doubt the results” (#1). However, some doubts occurred because the results and the users’ own experience of their sleep were not always similar. For one user (#2) it was surprising that the results showed that there was no deep sleep during the night. “I question the entropy – deepness of my sleep. Could it be that something is not right in the analysis in my case since I felt that I slept well?” He also commented: “Seeing from the sleep analysis that I did not move much during the night gives me extra confirmation that I indeed slept well.” Another user said: “My own impression was that I slept restlessly. However, according to the analysis I slept well” (#1). One user commented: “There were surprisingly many awakenings during the night. The position indicated me when I really was awake” (#4).

Background information and experience on sleep related issued affected on trust. “I am familiar with entropy due to my work so have learned to have confidence on it” (#5). However, some new features were found out: “The appearance of REM in different parts of the night made me a little confused. However, I know that making the analysis more accurate would need more from the device technically” (#5). Accordingly: “There were a lot of interruptions in my sleep analysis. I think that it is because I sleep on my stomach and the contact with the electrodes may get disturbed” (#3).

Sleeping position and entropy were seen the most interesting results. The participants found as the most interesting result seeing some new and even surprising information about their sleep. “I trust the information about how deep my sleep was. However, I found it strange that there were so many awakenings during the night” (#4). “It is interesting to see the sleeping position. I thought I sleep supine but the analysis tells me that I slept also on both right and left sides.”(#1) “The analysis told that my sleep was better than I myself thought” (#5).

In the sleep analysis many users had interest especially in percentage and hourly presentation of their sleep. It was also found useful to see own sleep analysis compared with an ideal analysis result, “a school book” version.

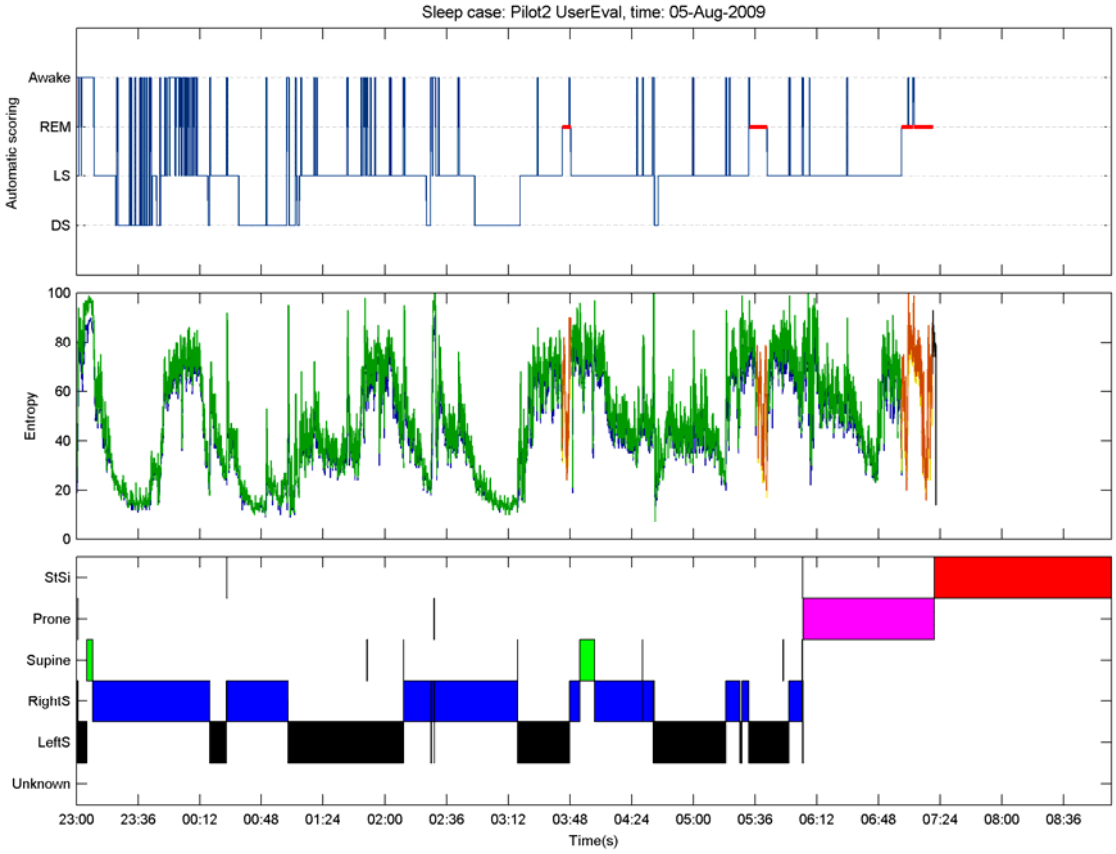

Figure 42 – The sleep analysis graphs of one of the pilot users. The upper graph shows sleep levels: Awake; REM=Rapid Eye Movement; LS= light sleep; DS= deep sleep. The middle graph is entropy. The lowest graph shows the sleeping position: Prone= on the stomach; Supine=on the back; RightS=on the right side; LeftS=on the left side

```
Pilot2 UserEval
05.08.09 23:00:00

Time in bed (TIB) - 8 h 20 min
Sleep latency to first 60 seconds of sleep (SOL) - 0 h 10
min
Wake time during sleep period (WASO) - 0 h 37 min
Total sleep time (TST) - 7 h 33 min

Sleep efficiency referred to time in bed (SEI) - 91%

Time in REM - 0 h 33 min (7%)
Time in light sleep - 5 h 35 min (74%)
Time in deep sleep - 1 h 26 min (19%)

Number of sleep stage transitions - 310
Number of sleep stage transitions per hour of sleep -
38.0
Number of sleep stage transitions from DS to W - 10

REM latency from sleep onset - 4 h 34 min
DS latency, from sleep onset to DS - 0 h 14 min

Number of REM periods - 3
```

```
Number of unconstrained REM periods - 5
Average REM period - 10.8 min
Shortest REM period - 4.5 min
Longest REM period - 18.0 min
Average interval between REM periods - 1 h 32 min

Number of DS periods - 3
Number of unconstrained DS periods - 14
Average DS period - 26.2 min
Shortest DS period - 19.0 min
Longest DS period - 33.0 min
Average interval between DS periods - 1 h 16 min
```

Figure 43 – The textual feedback of one of the pilot users sleep analysis

No user was missing additional information. It was mentioned that in the sleep analysis as such there is even too much data for an ordinary user. “Now the graphs look obscure” (#3). For ordinary users, a simpler bar graph with data about time spent in bed, duration of sleep accompanied with quality of sleep was seen adequate.

The users were ready to share the data with their doctor as well as with their family. The data was compared to blood pressure data regarding privacy (#4). But, “if there would have been something exceptional in the results I would like it to remain more confidential” (#4). One user stated: “I wouldn’t trust the data to a health nurse before a doctor has analysed the graphs” (#5). Thus, it was highlighted that doctor’s knowledge is needed to interpret the graphs.

5.3.6.4 Usefulness

The users found the system generally useful:
“When someone has sleeping problems the doctor can analyse if you do not sleep well or if you just assume so” (#1)
“Good to have data about sleep in black and white” (#1)
“Is useful in defining disorders but not useful for healthy people who feel that they sleep enough” (#4)

The system was found useful if the analysis helps to find ways to make one’s sleep better (#2). The system was assumed to be targeted for people who have sleeping problems (#2). One user also commented: “People are interested in themselves and about their health. This logger responds this need and can be compared to sphygmomanometer in this sense” (#3).

The development direction of the sleep logger was found twofold. Firstly, there could be a device for home use in the market. People who want to measure their sleep or e.g. the relation of the quality of their bed related to quality of sleep would have the possibility to receive a simple sleep analysis. It was ideated that already in the morning a small display attached to the logger would show a simple graph of the previous nights’ sleep (#2). According to the direct information of ones’ sleep people could pay attention to their sleeping habits as well as to their lifestyle. Secondly, the device could be useful in clinical sleep research with people who have serious sleeping problems. It would be much more comfortable to sleep at home than in a sleep laboratory (1, 5). Also, the costs when measuring sleep at home would be smaller compared to nights spent in a laboratory (#5). In addition, the reliability of the data was brought out since the environment during the research

would be the same as normally, that is, home (#5). One user (#4) saw the sleep logger as a device which could be loaned out from the health centre.

The participants were asked would if they would use the sleep logger if it would be available and if they would have the need to measure their sleep quality. Four of five users would be ready to use the device. One participant (#3) said that he doesn't use a sphygmomanometer either so maybe he would not be interested in using the sleep logger. The users were not asked about pricing but two users presented their estimates of an acceptable price for a device for home use as 100-150 € (#5) and 200-300 € (#3).

Based on their experiences all the test users would recommend the sleep logger to their friends of relatives. The logger would be recommended because it is easy (#5), it causes no harm to the user and also because collecting the data does not hurt (#4). However, it was doubted if elderly people would cope with the data transfer (#2).

The sleep analysis was seen useful e.g. for people who often wake up during small hours. The analysis would tell them that awakenings are normal during that time. The participant who pointed this out (#3) benefited from the analysis and he also thought that some people who might e.g. have sleep medication in vain would benefit from the sleep analysis. The same user (#3) however also pointed out: "People easily generate diseases for themselves. They should not get scared after the first measurements, but several successive measurements should be made."

5.3.6.5 Development ideas

Four test users pointed out that the logger should be smaller, "The smaller the better". Two of them suggested that the logger could be thinner if the snap connectors on the electrodes were replaced with some other solution. The users also suggested that the material of the logger could be more elastic, e.g. a band. In the final workshop these ideas were discussed and it was concluded that a band may however not be as good a solution as a separate device on the forehead.

Three test users proposed that on the logger base, there could be a hollow, where the logger would fit. This would ensure the right positioning and also would prevent moving the logger accidentally. One user also suggested that a separate LED indicating the logger positioned correctly would help (#3).

One of the test users (#4) thought that the appearance of the logger will need attention: "Current appearance brings into one's mind horror movies, it may feel frightening and it may give the impression that is conducts electronic current to the body. The user may wonder how the logger will influence one's brain overnight". The test user gave the following suggestions to be considered in designing the logger:

1. The logger should not look too technical
2. The logger should not be transparent; electronics should be hidden from sight
3. The colour of the logger can be selected to create a casual feeling
4. The guide book should also emphasize that the device will not harm your brain.

One user (#3) had problems in positioning the logger on the forehead. The right position should be indicated by an up marker, not left/right marker with which the mirror can confuse the user.

Some users were missing better feedback on the measurement starting and the logger being ready for data download. In the guidance, it should be explained that the measurement does

not start right away but the user has to wait for the measurement to start (even 10 minutes). Similarly, it should be emphasised that data download can be started despite the blinking led on the logger. These issues were corrected in the user guide after the two first test users. In the final workshop it was discussed whether the led will be needed at all. The device should be reliable enough so that the user can just put it on his/her forehead and rely that the measuring starts. However, the usability experts from VTT emphasised that users would like to have feedback on ongoing measurements. It was discussed also that it is important to get feedback that the logger battery is fully charged for the measurement.

One user (#2) wondered why one of the electrodes was on the temple with a wire, and suggested that all the electrodes could be on a row on the forehead. In the guidance it was not explained that the temple electrode was registering eye movement and thus necessary to be positioned on the temple. It would be beneficial to inform users about the basic principles of the device e.g. in the guidance.

With one user (#4) the electrodes caused itching, and the user was wondering if the adhesive was commonly causing this kind of symptoms.

Two users suggested that better feedback of the progressing of the data transfer would be needed. One of them (#3) suggested graphical feedback with a small LCD-unit on the box. One of the other users (#5) told that the LEDs were sufficient in following the transfer progress. One user (#2) suggested that the logger base could be battery operated.

Three users suggested that the mobile phone could be left away and the logger base could take care of transmitting the data to the server. One of them (#5) suggested that if the mobile phone is included, the phone could provide some added value like showing the data on the screen. Another user (#2) also suggested that some feedback: “a graph, how did I sleep” could be provided to the user right away. In the final workshop it was emphasised that also history data is important, especially in home use. The user can then identify how his/her habits affect the quality of sleep.

Two users suggested that the device could have both home version and professional version. The home version could include features that support self-control and give immediate feedback after the night. One user (#3) suggested that the professional version could include supporting measures such as “breath analyser to diagnose apnoea, oxygen saturation. A combination of SpO2, apnoea meter and sleep logger would be quite cool for a sleep laboratory.” In the final workshop it was discussed that heart rate measurements are also important part of the data and the existing logger could quite easily be modified so that it would also measure heart rate.

In the final workshop it was concluded that the consumer version could be based on PC or mobile phone software that could download the sleep data and send it to be analysed. The results could then be monitored and stored on the personal computer or mobile phone. It was emphasized that the analysis should be an external service; software alone without a human interpreter is not a good solution. The professional system should be an all-in-one solution, a logger base with embedded data connections. In that way, the device could be loaned to the patients as a “plug-and-measure” unit.

In the final workshop, the clinicians emphasized that the logger should be easy to keep clean. It also turned out that the time scale in the analysis graph was an estimate; the final logger should include a clock with exact time.

5.3.7 Conclusions

The main conclusion from the evaluation is that the concept is working: all five test users as well as the two pilot users could wear the logger overnight and it did not disturb their sleep much. Even it the users did not have specific sleep problems, the information of sleep data was felt interesting. For consumer use, even less information could be enough and easier to understand for the users.

The simplified sleep analysis with just two levels of sleep – deep and light – seems to work. However, with the traditional classification with 4 sleep levels, perhaps the users whose analysis included very little or not at all deep sleep might have got more thorough information. In the current system, the limit for deep and light sleep may require checking.

Both the test users and the GE representatives in the final workshop saw two parallel development paths: a consumer device and a professional device. For a consumer product, the analysis could and should be simpler, and include immediate feedback after the night. Professional version might require more supporting measurements. Consumer device could include the logger and a connector to read the data to PC or mobile phone. The professional version could include the logger and a logger base with integrated mobile phone or other data connection facility. In the consumer version, it would be important to give the results to the user right away or at least after a short analysis phase. In the professional version, the quick feedback to the user is not required because the results go to a professional to be analysed.

Annex- MINAmI Frontal EEG Logger Verification Protocol

GE Healthcare

MINAmI Frontal EEG Logger

Verification Protocol

Author: Petteri Lapinlampi

Table of contents

Change history

Date	By	Description of changes
13-Aug-2009	P. Lapinlampi	First version
14-Aug-2009	P. Lapinlampi	Corrections suggested by Juha Virtanen
14-Aug-2009	J. Virtanen	Typographical corrections

GE Healthcare

MINAmI Frontal EEG Logger
Verification Protocol

1 Test Information

1.1 Test type

X Full Test ___ Regression Test

1.2 Test Equipment

1.2.1 Test Device (write also serial/ID numbers)

EEG logger: 001

Logger Base: 001

Power Supply: Model 06215, 8V plug

Mobile Phone: N95 056 1823

1.2.2 Test Software (versions)

Analyzesleep.exe: 1.07

Logger2edf.exe: 1.05

MINAmI_T7_2.sisx: 1.07

1.3 Test Personnel

Name: Juha Vuntunen (Juha) Date: 14.8.09 Time/h: 4

Name: Juha Date: 15.8.09 Time/h: 3

Name: Juha Date: 16.8.09 Time/h: 5

2 Test Summary

2.1 Results

Conclusion of the test: **PASS / FAIL**

Identifiers of the observations recorded:

Total number of cases failed: —

Test Lead Approval: 17-AUG-2009 Petteri Lapinlampi

Date Signature

3 Background

3.1 Purpose and Scope of the Test

This test will check that the Frontal EEG data logger fulfills the specifications of the device defined in M1186205.

3.2 Experience required

Need to know how to use the EEG data logger and the HyperTerminal PC interface of the logger base.

3.3 Test Items / Equipment Needed

- EEG data logger
- Logger base
- Power supply (Nordic power)
- USB cable with mini-USB connector for the logger base and a normal connector for the PC
- Mobile phone (with Symbian S60 3rd edition software) equipped with the MINAmI software
- ECG electrodes (CFM-00-S/50)
- Computer equipped with: analyzesleep.exe, logger2edf.exe, HyperTerminal and a web browser software (Mozilla Firefox 3.0 or newer, IE6 or newer)

3.4 Estimated test time

3 days

3.5 Reference Documents

M1186205	D7.12 Final demonstrator requirements - Extract from the original document including Sleep Quality Analysis (T7.2) only

3.6 Definitions

EEG	Electroencephalography
TC	Test Case

4 Preparing the Test Environment

4.1 Equipment Setup

Connect the logger base to mains via the power supply.

Check that the power LED is lit on the logger base.

Check that the EEG logger is in standby mode, i.e., the LED is blinking every ten seconds. If not, place the logger on the base for ten seconds and check again.

4.2 Test Instructions

To connect the logger base to a PC with the USB cable the computer must have USB serial drivers installed.

5 Test Cases

Special Instructions

NONE

Test Case ID		EEGLOG_T72_01	
Description		Nightly logger recording	
Applicable for		EEG data logger	
Requirements		EEG-LOG-001, EEG-LOG-005	
Initial Conditions		Equipment is set up as per Equipment Setup section.	
Step	**Full / Regr**	**Task & Expected Result**	
1	F	Attach the logger and the electrodes on the forehead of a test subject and wait 20 seconds.	
2	F	Verify: The led on the logger is blinking once per second.	**Pass / Fail**
3	F	Detacht the logger and measure the time until the logger LED stops blinking: 10 h 5min Expected result: at least 10 h	**Pass / Fail**

Comments: 1. 12s to start blinking

JMaV 14.8.09

Tester: Date:

GE Healthcare

MINAmI Frontal EEG Logger
Verification Protocol

Test Case ID	EEGLOG_T72_02	
Description	Logger reading and recharging	
Applicable for	EEG data logger	
Requirements	EEG-LOG-004, EEG-LOG-007, EEG-LOG-008, EEG-RDR-001, EEG-RDR-002, EEG-RDR-003, EEG-RDR-004	
Initial Conditions	Test case EEGLOG_T72_01 completed.	
Step	**Full / Regr**	**Task & Expected Result**
4	F	Place the logger on the logger base measure data readout time.
5	F	The readout time was: 15 minutes Expected value: less than 30 minutes
6	F	Attach the logger on the forehead to start a recording.
7	F	Wait 10 minutes and detach the logger.
8	F	Wait 12 hours for the batteries to wear out.
9	F	Place the logger on the logger base to perform data transmission.
10	F	Check which indicator LEDs are lit in the logger base: power, charging Expected result: Power, charging
11	F	Wait until the charging LED is turned off.
12	F	Verify: Data transmission starts (the "1/4" indicator LED is lit)
13	F	After the data transmission is completed connect the logger base to a computer via the USB interface and connect to the base with a hyperterminal.
14	F	Check the content of the logger memory: FF H Expected result: memory empty (all 'ff')
15	F	Attach the logger on the forehead to start a recording.
16	F	Wait 10 minutes and detach the logger.
17	F	Place the logger on the logger base to start data transmission.
18	F	After 5 minutes of data transmission raise the logger 5 cm above the base for 10 seconds.

		Pass / Fail
		Pass / Fail
		Pass / Fail
		Pass / Fail

GE Healthcare

MINAmI Frontal EEG Logger
Verification Protocol

19	F	Verify (using the hyperterminal interface) that data transmission is interrupted when the logger is lifted and continued when the logger is put back on the base.	Pass / Fail
20	F	Check the content of the logger memory: FFH often Expected result: memory empty (all 'ff') after 10 minutes 1200 blocks	Pass / Fail

Comments:

Juha V 15.8.09

Tester: Date:

GE Healthcare

MINAmI Frontal EEG Logger
Verification Protocol

Test Case ID		EEGLOG_T72_03	
Description		Observational test of the system	
Applicable for		EEG data logger	
Requirements		EEG-LOG-002, EEG-LOG-003, EEG-LOG-006, EEG-LOG-009, EEG-CHR-001, EEG-CHR-002, EEG-ANL-003	
Initial Conditions		Equipment is set up as per Equipment Setup section.	
Step	**Full / Regr**	**Task & Expected Result**	
21	F	Observe the material and surface structure of the logger.	
22	F	Verify: the material specification indicates that the material is smooth to facilitate cleaning, withstands disinfectants, and is biocompatible.	**Pass / Fail**
23	F	Attach the logger to the forehead.	
24	F	Verify: no other parts than the electrode contacts are in contact with the skin.	**Pass / Fail**
25	F	Measure the weight of the logger: Weight: 60 g Expected value: less than 50g	**Pass / Fail**
26	F	Measure the dimensions of the logger: Height: 40 mm, length: 30 mm, width: 10 mm Expected values: height less than 40 mm, length less than 60 mm, width less than 20 mm.	**Pass / Fail**
27	F	Check the maximum number of recharging events of the logger batteries from their data sheet: 1000 times Expected result: at least 100	**Pass / Fail**
28	F	Observe the logger base.	
29	F	Verify: The base comprises a single entity including reader and charger.	**Pass / Fail**
30	F	Verify: The base has indicator LEDs for main functions and an error LED.	**Pass / Fail**
31	F	Observe the sleep analyzer software on a PC.	
32	F	Verify: The software accepts input data file name as a parameter.	**Pass / Fail**
33	F	Verify: The software writes the analysis results in multiple files.	**Pass / Fail**

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MINAmI Frontal EEG Logger
Verification Protocol

Comments: 22. Biocomp. affected. Silicon can be cleaned with alcohol: www.standard-gasket.com/tech_specs/chem_res/chemical_resistance.html

Tester: JMcU Date: 14.8.09

27. Datasheet affected.

25. & 26. Exceeding weight and dimension spec. does not affect the performance of sleep study.

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Test Case ID		EEGLOG_T72_04	
Description		Configuration of the mobile application	
Applicable for		EEG data logger	
Requirements		EEG-MOB-002, EEG-MOB-006	
Initial Conditions		Equipment is set up as per Equipment Setup section.	
Step	**Full / Regr**	**Task & Expected Result**	
34	F	Start the MINAmI software on a mobile phone and turn on BlueTooth connection.	
35	F	Verify: The phone detects the logger base and the BlueTooth pairing is successful.	**Pass / Fail**
36	F	Configure server settings in the mobile application.	
37	F	Run the "test configuration" request in the mobile application.	
38	F	Verify: The application sends the test configuration request and receives ACK confirmation from the server.	**Pass / Fail**

Comments:

JuanV 14.8.09

Tester: Date:

Test Case ID		EEGLOG_T72_05	
Description		Transfer data to server	
Applicable for		EEG data logger	
Requirements		EEG-MOB-001, EEG-MOB-002, EEG-MOB-003, EEG-MOB-004, EEG-MOB-006, EEG-MDS-001	
Initial Conditions		Equipment is set up as per Equipment Setup section.	
Step	**Full / Regr**	**Task & Expected Result**	
39	F	Run the "Send data" request on the mobile application.	
40	F	Verify: The mobile phone starts to receive the data from the base.	**Pass / Fail**
41	F	Verify: The mobile application displays an information note when data has been received and proceeds automatically to sending the data to the server.	**Pass / Fail**
42	F	Verify: The data transfer begins and ends.	**Pass / Fail**
43	F	Repeat steps 40 to 42.	
44	F	Cancel the data sending to the server.	
45	F	Verify: The data is stored in the mobile phone to be sent at a later occasion.	**Pass / Fail**

Comments: 41. Phone requires confirmation of authentification. Does not affect analysis performance.

JMaV 16.8.09

Tester: Date:

GE Healthcare

MINAmI Frontal EEG Logger
Verification Protocol

Test Case ID		EEGLOG_T72_06	
Description		Visualize data	
Applicable for		EEG data logger	
Requirements		EEG-MDS-002, EEG-MDS-004, EEG-MDS-005, EEG-MDS-007, EEG-MDS-008	
Initial Conditions		Equipment is set up as per Equipment Setup section.	
Step	**Full / Regr**	**Task & Expected Result**	
46	F	Start a web browser and open the URL for the medical server application.	
47	F	Verify: A username and password are requested.	**Pass / Fail**
48	F	Verify: Access is denied when using a random username and/or password.	**Pass / Fail**
49	F	Enter valid username and password.	
50	F	Verify: Access is granted to the server.	**Pass / Fail**

Comments:

JJ V 16.8.09

Tester: Date:

Test Case ID		EEGLOG_T72_07	
Description		View messages and patient notification	
Applicable for		EEG data logger	
Requirements		EEG-MOB-002, EEG-MOB-005, EEG-MDS-003, EEG-MDS-004, EEG-MDS-006, EEG-MDS-007	
Initial Conditions		Equipment is set up as per Equipment Setup section.	
Step	**Full / Regr**	**Task & Expected Result**	
51	F	Access the server with a web browser software.	
52	F	Verify: Notifications can be sent to patients in SMS format	**Pass / Fail**
53	F	Send SMS notification to a mobile phone.	
54	F	Verify: The mobile phone receives the SMS and is able to visualize it to the patient.	**Pass / Fail**

Comments:

Jaka V 16.8.09

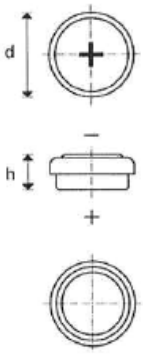
Tester: Date:

VARTA

V 40 H

Rechargeable Ni-MH Button

Data Sheet



Type Number:	55604	
System:	Nickel Metal Hydride/ KOH Electrolyte	
Nominal Voltage [V]:	1.2	
Nominal Capacity C [mAh]:	40	
Typical Capacity C [mAh]:	43	
at 8 mA / 1.00 V		
Weight, approx. [g]	1.7	
Dimensions [mm]:	**min.**	**max.**
Diameter [d]:	11.3	11.5
Height [h]:	5.05	5.35
UL Recognition:	MH 13654 (N)	
Coding:	Manufacturing 5 digit code (123 = day/4 = year/ 5 = version)	
Temperature Ranges [°C]	**min.**	**max.**
Storage: less than 30 days	-40	65
Discharge:	-20	65
Charge:	0	65
Charging Method:		
Normal Charging:	4 mA for 14 – 16 h	
Accelerated Charging (20°C):	8 mA for 7-8 h	
Fast Charging:	20 mA for 3 h *	
Time controlled, voltage control recommended		
Trickle Charging:	1.2 mA	
Overcharge (20°C):	4 mA continuous	
	8 mA up to 1 year	
Charge Retention [%] at 20°C:	90	
Capacity available after 1 month Storage at 20°C		
Internal Resistance [Ohm]:	3	
at charged cells, 20°C, DC: 0.2 CA/2 CA, (IEC 61951-2)		
Impedance [Ohm]:	0.42	
at charged cells, 20°C, AC: 1kHz, (IEC 61951-2)		
Typical Capacities [mAh]:		
at 40 mA / 0.90 V	23	
Max. Discharge Current (cont.) [mA]:	80	
Life Expectancy (typical):		
IEC Cycle:	1000 Cycles	
Trickle Charge:	up to 6 years (20°C)	
Trickle Charge:	up to 3 years (45°C)	

* for fully discharged cells, 20 °C

Capacities based on normal charging

VARTA Microbattery GmbH, Daimlerstraße 1, D-73479 Ellwangen/Jagst
Tel.: (+49) 7961/921-0, Telefax: (+49) 7961/921-553

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Date of Issue: 04-05-19

WACKER SILICONES

Evaluation of Biocompatibility for

WACKER ELASTOSIL® M 4641 A/B

Toxicological tests on **WACKER ELASTOSIL® M 4641 A/B** have not been carried out. However, irritation, sensitization and cytotoxicity tests according to the ISO 10993 standard with different two component addition curing silicones of similar base materials have been performed and did not show any adverse effects.
Based on this analogy and the toxicological properties of the ingredients it is expected that **ELASTOSIL® M 4641 A/B** will not cause skin irritation, sensitization or cytotoxic effects .
Provided that the material is appropriately cured/postcured **ELASTOSIL® M 4641 A/B** is not expected to cause any adverse effects in humans at direct contact with skin.

Wacker-Chemie AG

Dr. C. Burger
GB-S-IMS Manager Product Stewardship 1

Burghausen, May 09, 2008

biocompatibility_M 4641.doc